



nCounter®

Dx Analysis System User Manual



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For In Vitro Diagnostic Use

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1 Introduction

A. Product Use Limitations

The nCounter Dx Analysis System and the nCounter Dx Analysis System with the FLEX configuration (when run in IVD mode) is intended for *in vitro* diagnostic use when used in conjunction with specific IVD cleared or approved assays citing its use. The nCounter Dx Analysis System may only be used with NanoString's nCounter test kits.

The nCounter Dx Analysis System may only be operated by appropriately trained, professional users. NanoString recommends that all users read and understand this manual prior to attempting to operate the system. Keep this manual in close proximity to the instruments for easy access to instructions and safety information. Failure to comply with the instructions in this manual may pose a dangerous risk to the operator and void the manufacturer's warranty.

B. Product Components

The nCounter Dx Analysis System consists of two instruments: the Prep Station and the Digital Analyzer. A power cable is included with each instrument. The Prep Station also includes a pipette tip rack, a liquid waste container, a solid waste container, and silicone grease.

In addition to instrument software, a web-based software application (web application) is provided to configure runs, to observe sample statuses, and to download sample reports.

C. Overview of the Procedure

1. The web application is used to identify and annotate samples and define the test to be performed.
2. After sample processing and hybridization has been completed according to the test kit instructions, samples are inserted into the Prep Station for purification and immobilization onto the internal surface of a sample cartridge (2-3 hours, depending on the number of samples).
3. The sample cartridge is then transferred to the Digital Analyzer for imaging and analysis (about 4.5 hours, or 20-25 minutes per sample).
4. During processing with the nCounter Dx Analysis System, the web application may be used to track sample statuses.
5. Finally, test reports are available for download using the web application.

D. Manual Conventions

The following conventions are used throughout this manual and are described for your reference.

Text Style	Meaning
Bold	Bold text is typically used to highlight a specific button, keystroke, or menu option. Bold text may appear elsewhere to highlight important text or terms.
<i>Italic</i>	Italic text is typically used to highlight references to another section or chapter of the manual. Italic text may also be used to highlight references to other manuals or instructional material.
Blue	Blue text is typically used to highlight references to specific figures or tables. Blue text may also be used to indicate active hyperlinks to online content or e-mail addresses.



NOTE: This symbol indicates general information that may be useful when performing assays. These notes may clarify other instructions or provide guidance to improve the efficiency of the assay workflow.



IMPORTANT: This symbol indicates important information that is critical when performing an assay.



CAUTION: This symbol indicates the potential for bodily injury or damage to the instrument if the instructions are not followed correctly. Always carefully read and follow the instructions accompanied by this symbol to avoid potential hazards.

E. Instrument Specifications

Test Samples per Run	1-10
Weight	Prep Station 5s: 265 lbs. / 120 kg
	Digital Analyzer 5s: 150 lbs. / 68 kg
Dimensions (W x D x H)	Prep Station 5s: 35.0 x 26.4 x 24.6 in. / 89 x 67 x 63 cm
	Digital Analyzer 5s: 26 x 26 x 19 in. / 66 x 66 x 48 cm
Power Requirements	100-240 VAC, 610 VAC
Fuse	8A (100-120 VAC) or 4A (200-240 VAC)

F. Additional Precautions

- The Digital Analyzer is a Class 1 laser product, and the instrument contains an internal Class 2 laser barcode reader. Class 2 laser radiation exposure is possible while the Digital Analyzer cover is opened. Do not stare into the barcode reader laser beam.
- The Prep Station contains high voltage and heater modules indicated by symbols on the deck. Avoid contacting the heater module and electrodes. The instrument is equipped with a safety interlock that will prevent voltage from being applied while the instrument door is open.
- Do not use this device in close proximity to sources of strong electromagnetic radiation or vibration, which may interfere with proper operation.
- Do not attempt to install, move, or disassemble the instruments.
- Do not override the door sensors (a pinch hazard exists).
- Ensure that all consumables are properly inserted into the system prior to starting a procedure.
- Operate the system using only NanoString nCounter test kits in accordance with their Intended Use.
- Wear gloves while operating or performing user maintenance on the instruments.
- Do not attempt to wash the Prep Station's electrodes or allow water or other solvents to come into contact with the electrodes.
- Do not attempt to wash either instrument's touchscreen or allow water or other solvents to come into contact with the touchscreens.

G. Caution Symbols



BIOHAZARD: Potential hazard from a biological source exists. If you choose to use biohazardous materials on your Prep Station, the instrument may become contaminated with biohazardous materials. Please affix the proper warning labeling to your Prep Station if you use biohazardous inputs. Be careful not to touch this area without gloves or other personal protective equipment.



ELECTRICAL HAZARD



CAUTION HOT SURFACE

H. Environmental Requirements

- Temperature: 18-28°C
- Humidity: < 80% relative humidity (non-condensing)

2 Hardware Overview

A. General Information

The instrument serial number and compliance information can be found on the rating plate on the back panel of each instrument. Please refer to the rating plate and declaration of conformity (EU only) for compliance information.

Both instruments contain a touchscreen to enable operation of the instrument. The touchscreen is a touch-sensitive method of controlling the instrument that enables the user to operate the system by touching a selection on the screen. There are several buttons that appear in the touchscreen user interface. For example:

- **Next** – Proceeds to the next screen.
- **Back** – Moves back to the previous screen.
- **Cancel** – Returns to beginning of the current workflow or the main menu.

B. Prep Station

The Prep Station is a multi-channel pipetting robot configured specifically for use with NanoString nCounter Test Kits. The instrument performs liquid transfers, magnetic bead separations, and immobilization of molecular labels on the sample cartridge surface (**FIGURE 2.1**).



FIGURE 2.1: The Prep Station

The Prep Station deck must be loaded with the appropriate consumables prior to use (**FIGURE 2.2**).

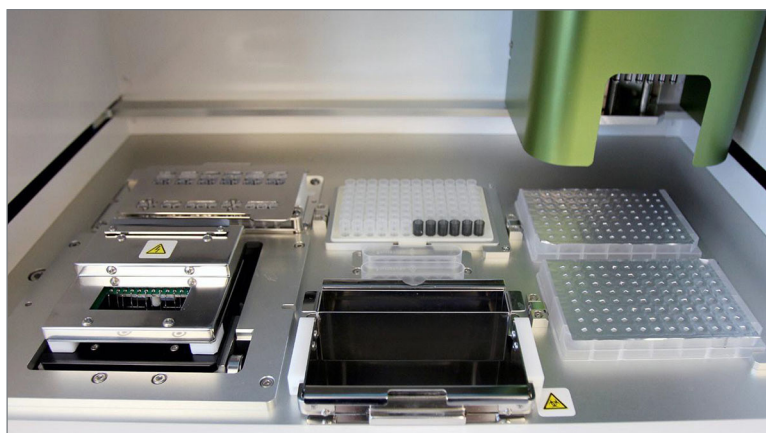


FIGURE 2.2: The Prep Station Deck

C. Digital Analyzer

The Digital Analyzer is a multi-channel epifluorescence scanner configured specifically for use with NanoString's nCounter Test Kit Cartridges. Up to six cartridges can be loaded into the instrument (**FIGURE 2.3**). When one or more scans have been completed, the instrument may be paused to allow new cartridges to be swapped in without disrupting the remaining cartridges.



FIGURE 2.3: The Digital Analyzer

3 Selecting the Instrument Mode

Users who have the FLEX configuration are able to run their instruments in either Life Sciences or Diagnostics (Dx) application modes. The FLEX configuration must be enabled by NanoString Support.



NOTE: If the FLEX configuration has not been enabled, the instructions provided in this chapter will not apply; only the Diagnostics application mode will be available. Proceed to Chapter 4.

All NanoString IVD assays must be performed using the Diagnostics mode on these instruments. In Diagnostics mode, there are procedures and controls in place that restrict access to data and some features to authorized users. For all other applications, individuals using nCounter CodeSets or nCounter Elements should choose the Life Sciences mode and refer to the *nCounter Analysis System User Manual* for further instruction.

A. Prep Station

Select Instrument Mode

After turning on the Prep Station, the first screen to appear asks the user to select either Diagnostics mode (blue, on the left) or Life Sciences mode (green, on the right).

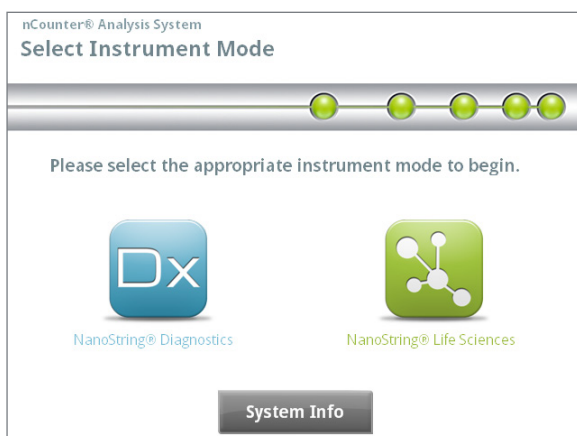


FIGURE 3.1: The Prep Station 'Select Instrument Mode' screen

Touch the blue icon labeled **NanoString® Diagnostics** to enter Diagnostics mode. The system will load the application and present the Welcome screen (FIGURE 3.2). Before operating the Prep Station, a user must log on by selecting the **Main Menu** button.

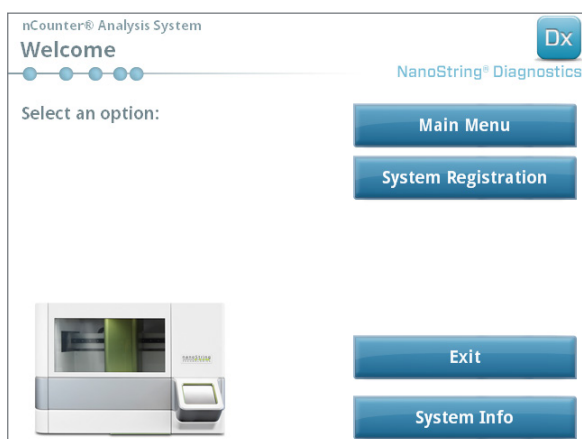


FIGURE 3.2: The 'Welcome' screen

>>> The sign in screen will appear (FIGURE 3.3)

Enter a valid user name and password and touch the **Sign In** button.

The sign in screen displays the title "nCounter® Analysis System" and "Please enter a user name and password". A progress bar with four dots is shown, with the first dot filled. The "User Name" field contains "Test User" and the "Password" field contains "*****". A virtual keyboard is displayed below the input fields. At the bottom right, there is a "Dx" button and the text "NanoString® Diagnostics". At the bottom, there are "Close" and "Sign In" buttons.

FIGURE 3.3: The sign in screen

>>> The Main Menu will appear (**FIGURE 3.4**).

The Main Menu screen displays the title "nCounter® Analysis System" and "Main Menu". A progress bar with four dots is shown, with the first dot filled. The "Logged In: Test User" text is displayed. There are five buttons: "Process Samples", "Maintenance", "Exit", "Sign Out", and "System Info". At the bottom right, there is a "Dx" button and the text "NanoString® Diagnostics".

FIGURE 3.4: The Prep Station Main Menu in Diagnostics mode

Switch Instrument Mode

The user may switch between Diagnostics mode and Life Sciences mode from the Main Menu. Press the **Exit** button located at the bottom of the Main Menu ([FIGURE 3.4](#)).

>>> The 'Exit Diagnostics Mode' confirmation screen will appear.

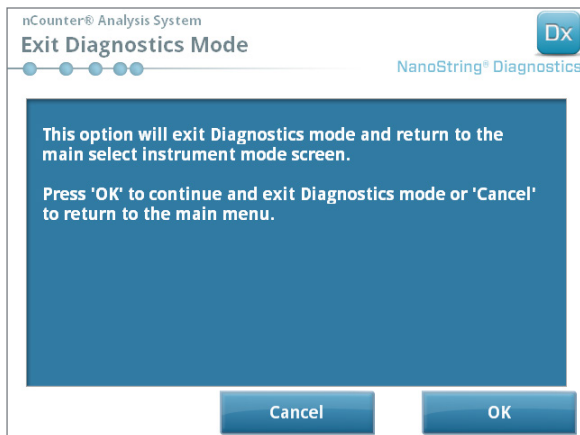


FIGURE 3.5: The Prep Station 'Exit Diagnostics Mode' confirmation screen

Touch **OK** to exit Diagnostics mode and return to the 'Select Instrument Mode' screen ([FIGURE 3.1](#)). Touch **Cancel** to return to the Main Menu.

B. Digital Analyzer

Select Instrument Mode

After turning on the Digital Analyzer, the first screen to appear asks the user to select either Diagnostics mode (blue, on the left) or Life Sciences mode (green, on the right).

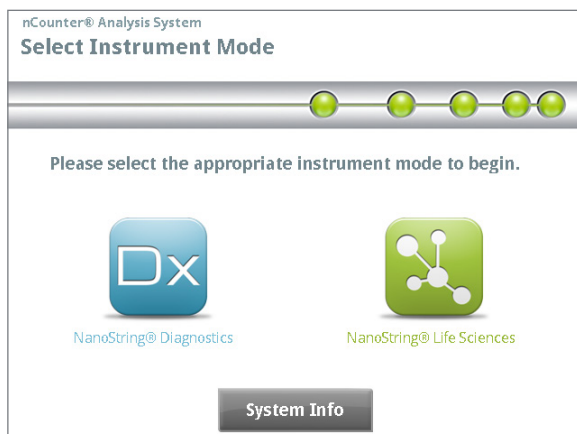


FIGURE 3.6: The Digital Analyzer 'Select Instrument Mode' screen

Touch the blue icon labeled **NanoString® Diagnostics** to enter Diagnostics mode. The system will load the application and present the Welcome screen (FIGURE 3.7). Before operating the Digital Analyzer, a user must log on by selecting the **Main Menu** button.

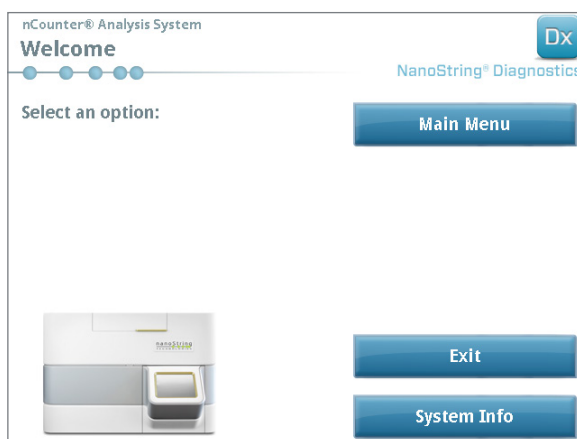


FIGURE 3.7: The 'Welcome' screen

>>> The sign in screen will appear (FIGURE 3.8).

Enter a valid user name and password and press the **Sign In** button.

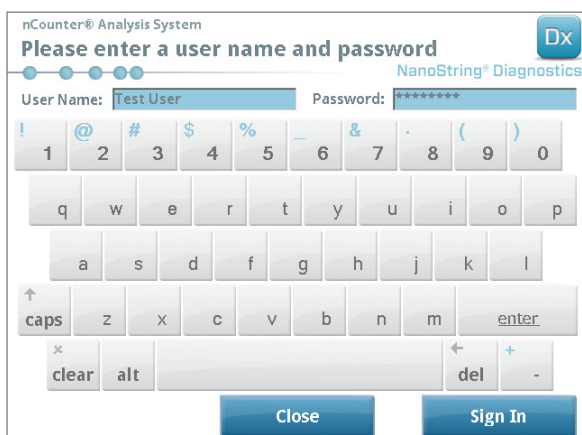
The image shows a web-based sign-in interface for the nCounter Analysis System. At the top, it says "nCounter® Analysis System" and "Please enter a user name and password". There is a "Dx" button in the top right corner. Below the title, there are two input fields: "User Name:" with the text "Test User" and "Password:" with masked characters "*****". Below the input fields is a virtual keyboard with buttons for numbers 1-0, letters q-w, e-r, t-y, u-i, o-p, a-s, d-f, g-h, j-k, l, and a row with caps, z-x, c-v, b-n, m, and an enter key. At the bottom right, there are two buttons: "Close" and "Sign In".

FIGURE 3.8: The sign in screen

>>> The Main Menu will appear (**FIGURE 3.9**).

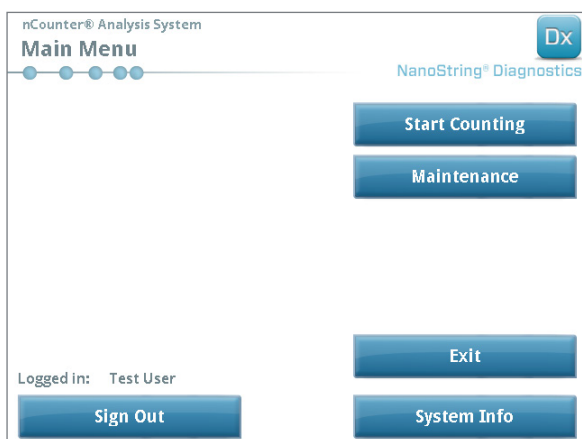
The image shows the Main Menu screen for the nCounter Analysis System. At the top, it says "nCounter® Analysis System" and "Main Menu". There is a "Dx" button in the top right corner. Below the title, there are four buttons: "Start Counting", "Maintenance", "Exit", and "System Info". At the bottom left, it says "Logged in: Test User" and there is a "Sign Out" button.

FIGURE 3.9: The Digital Analyzer Main Menu in Diagnostics mode

Switch Instrument Mode

The user may switch between Diagnostics mode and Life Sciences mode from the Main Menu. Press the **Exit** button located at the bottom of the Main Menu (**FIGURE 3.9**).

>>> The 'Exit Diagnostics Mode' confirmation screen will appear.

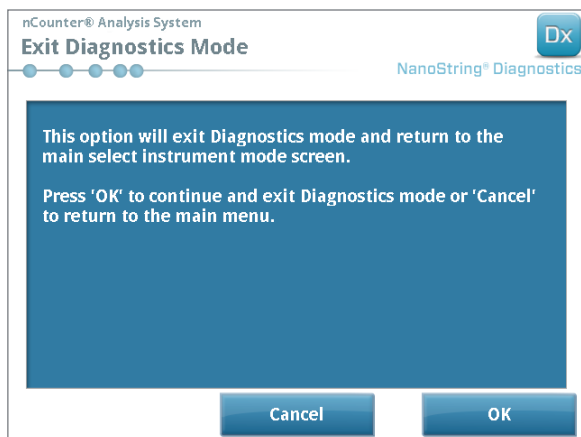


FIGURE 3.10: The Digital Analyzer 'Exit Diagnostics Mode' confirmation screen

Touch **OK** to exit Diagnostics mode and return to the 'Select Instrument Mode' screen (**FIGURE 3.6**). Touch **Cancel** to return to the Main Menu.

4 Operating the Web Application

This chapter provides directions for using the nCounter web application, which resides on a server contained within the nCounter Digital Analyzer. When the system is connected to a network, the web application can be used to communicate with both the Prep Station and the Digital Analyzer. Its primary functions are as follows:

- Create and edit Run Sets
- View the statuses of Run Sets
- Download reports
- Perform administrative functions

A. Sign In and Profile Management

Sign In

The local nCounter system administrator must provide each user with the URL to access the nCounter web application and will also set up the user account. Navigate to the URL provided from any computer connected to the organization's local network. (It must be the same network used by the Digital Analyzer.) The sign in page will appear. Enter the user ID and password provided by the administrator, select the desired assay type, and click **Sign In** (FIGURE 4.1).

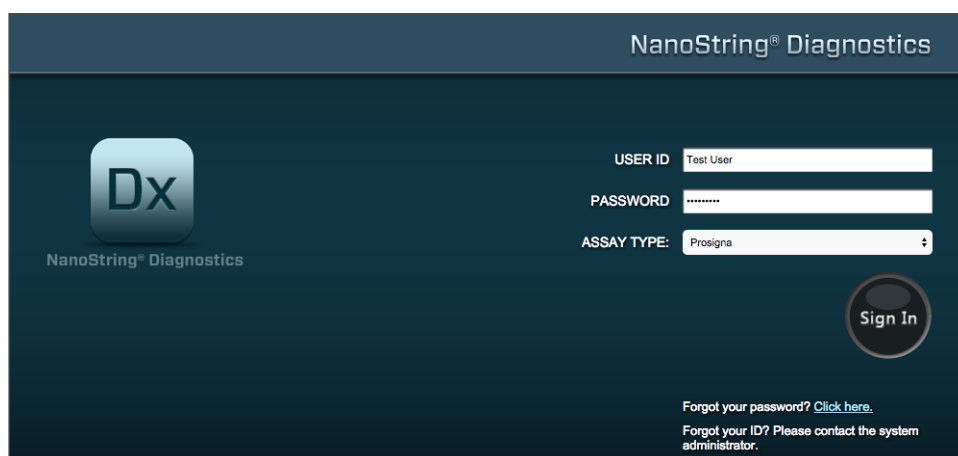
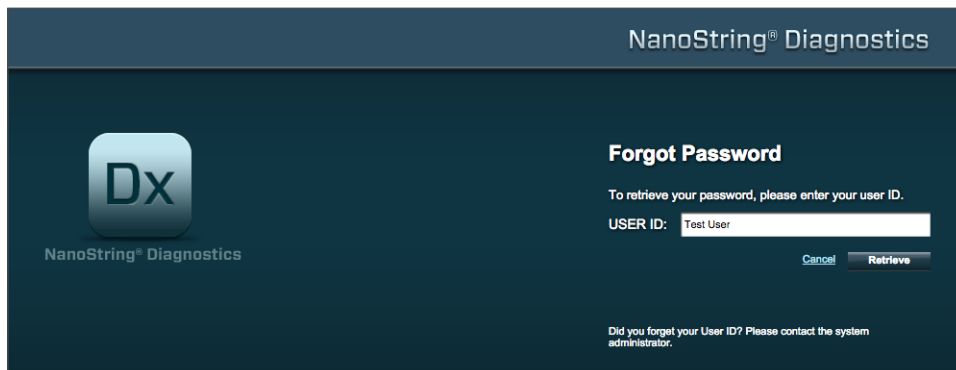
The image shows the sign-in interface for the NanoString Dx web application. The header at the top right reads "NanoString® Diagnostics". On the left, there is a logo consisting of a blue square with the letters "Dx" in white, and the text "NanoString® Diagnostics" below it. On the right side, there are three input fields: "USER ID" with the text "Test User" entered, "PASSWORD" with masked characters "*****", and "ASSAY TYPE" with a dropdown menu showing "Prosigna". Below these fields is a circular "Sign In" button. At the bottom right, there are two links: "Forgot your password? [Click here.](#)" and "Forgot your ID? Please contact the system administrator."

FIGURE 4.1: The nCounter web application sign in page

Forgot User ID/Password

If the user ID is forgotten, contact the local nCounter system administrator to retrieve it.

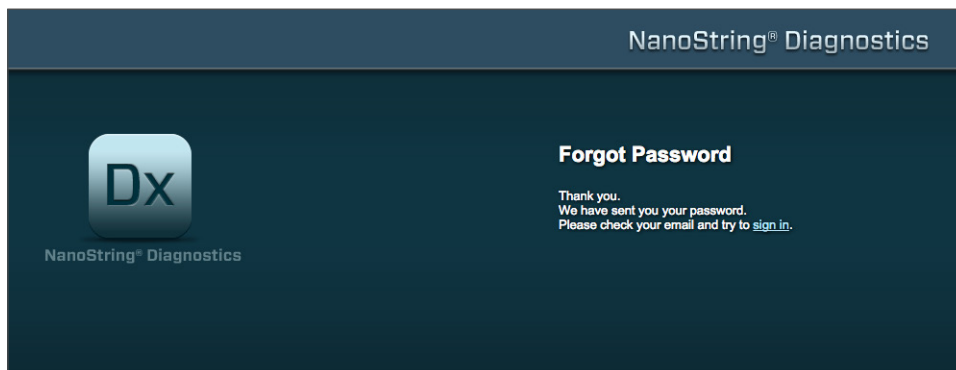
If the password is forgotten, the nCounter web application may be able to retrieve it. Click the link next to “Forgot your password?” to access the forgotten password submission page (**FIGURE 4.2**).



The screenshot shows the 'Forgot Password' page of the NanoString® Diagnostics web application. The page has a dark blue header with the text 'NanoString® Diagnostics'. On the left, there is a logo consisting of a blue square with 'Dx' in white, and the text 'NanoString® Diagnostics' below it. On the right, the title 'Forgot Password' is displayed. Below the title, a message reads: 'To retrieve your password, please enter your user ID.' There is a text input field labeled 'USER ID:' containing the text 'Test User'. To the right of the input field are two buttons: 'Cancel' and 'Retrieve'. At the bottom right, a small message states: 'Did you forget your User ID? Please contact the system administrator.'

FIGURE 4.2: The forgotten password submission page

Enter the user ID. If the nCounter system finds a matching profile, the password will be e-mailed to the address on record (**FIGURE 4.3**). If a matching profile is not found, the user will be instructed to contact the nCounter system administrator in order to reset the password.



The screenshot shows the 'Forgot Password' confirmation page of the NanoString® Diagnostics web application. The page has a dark blue header with the text 'NanoString® Diagnostics'. On the left, there is a logo consisting of a blue square with 'Dx' in white, and the text 'NanoString® Diagnostics' below it. On the right, the title 'Forgot Password' is displayed. Below the title, a message reads: 'Thank you. We have sent you your password. Please check your email and try to [sign in](#).'

FIGURE 4.3: The forgotten password confirmation page

Updating My Profile

User information can be updated by selecting the **My Profile** button from the menu bar at the top of the page (FIGURE 4.4).

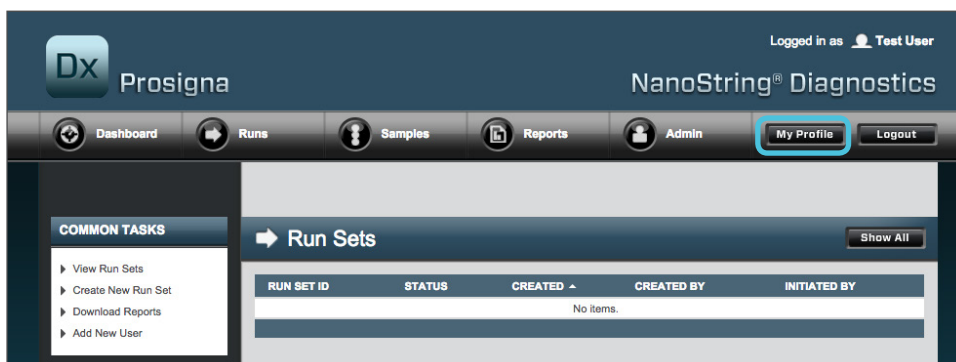


FIGURE 4.4: Location of the **My Profile** button

The 'My Profile' page enables the user to change the account password and/or e-mail address associated with the profile and view other account information (FIGURE 4.5). See *Section G: Manage Users* for more information about user types and privileges.

 The 'My Profile' page displays the following fields and options:

- USER ID:** Test User
- PASSWORD:** [masked]
- CONFIRM PASSWORD:** [masked]
- E-MAIL ADDRESS:** testuser@nanosttring.com
- USER TYPE:**
 - ☒ Administrator
 - ☐ General (no admin privileges)
- PERMISSIONS:**
 - RUN POST HYBRIDIZATION:**
 - ☒ Prosigna
 - ☐ Assay 2
 - ACCESS DATA:**
 - ☒ Prosigna
 - ☐ Assay 2
 - CREATE RUNSET:**
 - ☒ Prosigna
 - ☒ Assay 2

 At the bottom are 'Cancel' and 'Save' buttons.

FIGURE 4.5: The 'My Profile' page

To accept any changes made to a profile, click the **Save** button. To discard any changes and return to the previous page, click the **Cancel** button.

B. Application Layout and Navigation

Menu

The nCounter web application has a menu bar at the top that enables users to quickly navigate from one area of the application to another (FIGURE 4.6). The menu items separate the application into five sections:

- **Dashboard** – Common tasks and statuses of recent activities
- **Runs** – Create a Run Set and view run statuses (a Run Set consists of 1-10 diagnostic samples and two mandatory reference samples processed at the same time)
- **Samples** – View sample status
- **Reports** – Download reports
- **Admin** – Manage users and other system settings

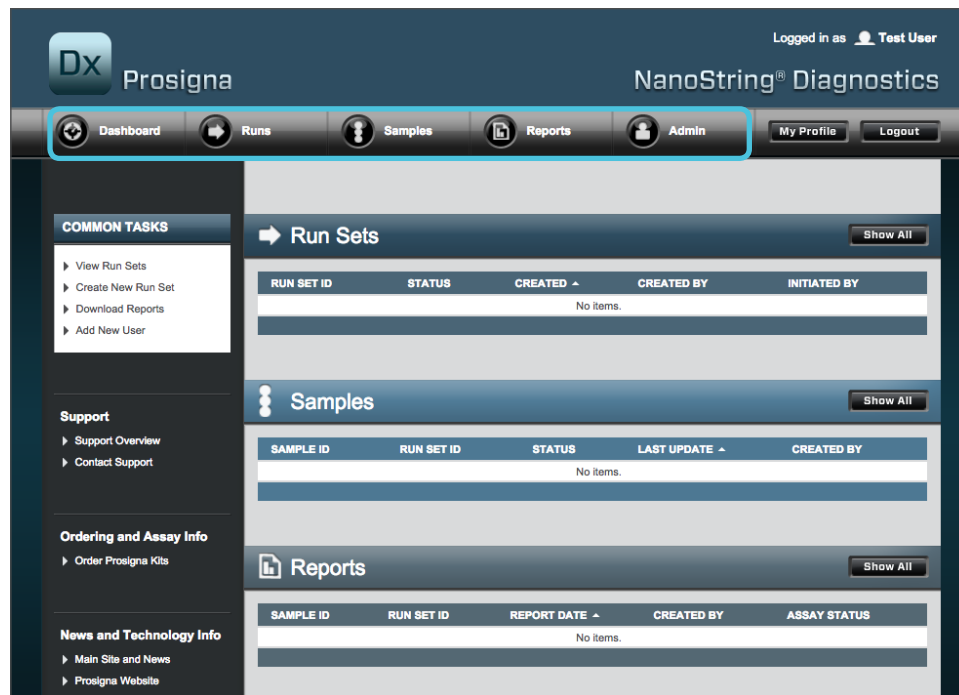


FIGURE 4.6: The web application main menu.

Most of the menu options have sub-menus that are available when a user hovers over the item (FIGURE 4.7). If no sub-menus are available, the user may simply click on the menu item.

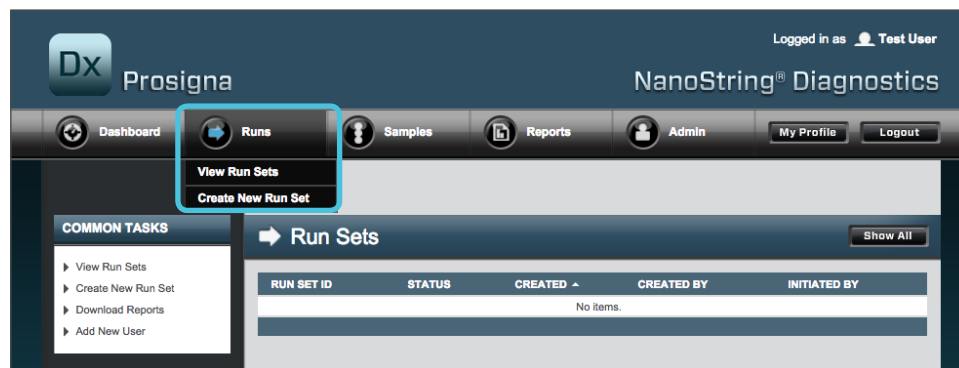


FIGURE 4.7: Sub-menus are available for some menu options.

Tables

The nCounter web application displays tables to quickly view Run Set statuses, sample statuses, users, and reports.

Filter

Tables can become large after frequent use of the nCounter web application, making it difficult to find the data of interest. Filtering is available in all tables to enable users to search for and view only data of interest.

By default, filtering is turned off for most status pages. (There is one exception: reference samples are filtered out by default on the 'Samples' page.) To turn filtering on, click on the '+' next to the Filter Settings header. The header will expand and display available filter settings (FIGURE 4.8).

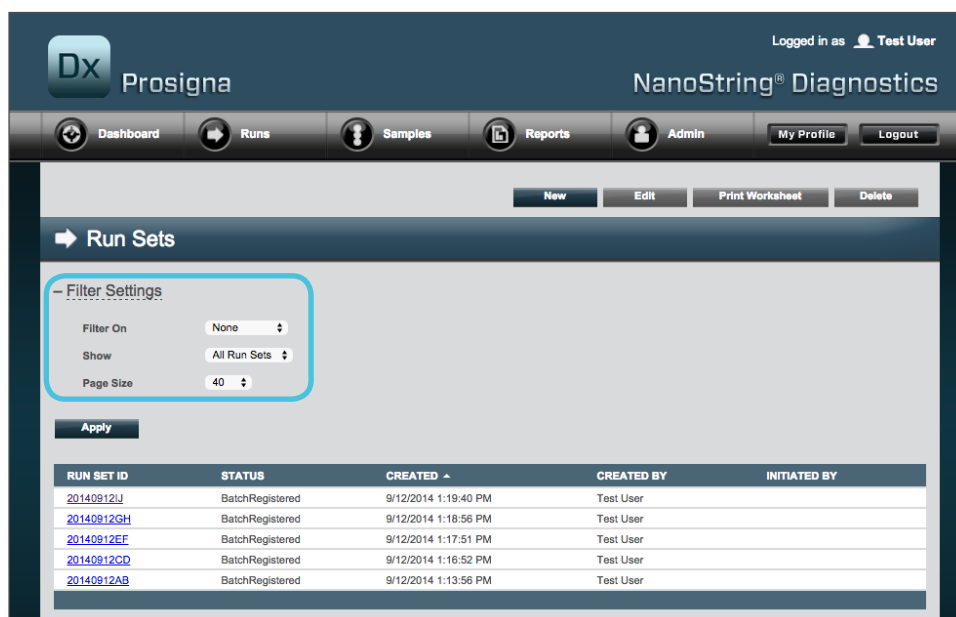


FIGURE 4.8: Filter settings are available when viewing most data



NOTE: Filtering is not available for the 'Manage Users' page.

Users can filter data by using any of the fields displayed in the table. This will return any items that match the entered text anywhere in that field. Likewise, users can choose to show all items or only items created recently by specifying the time frame of interest. To change the number of items displayed per page, select the desired page size from the drop down menu.

Run Sets

– Filter Settings

Filter On: Run Set Id match AB

Show: All Run Sets

Page Size: 40

Apply

FIGURE 4.9: An example of filter settings on the 'Run Sets' page

Click **Apply** when finished. Only relevant rows will be displayed in the table (FIGURE 4.10).



NOTE: The presence or absence of a funnel icon next to the page title indicates whether or not filtering is applied.

Run Sets

– Filter Settings

Filter On: Run Set Id match AB

Show: All Run Sets

Page Size: 40

Apply

RUN SET ID	STATUS	CREATED	CREATED BY	INITIATED BY
20140912AB	BatchRegistered	9/12/2014 1:13:56 PM	Test User	

FIGURE 4.10: An example of the funnel icon and filtered results on the 'Run Sets' page

Different filters are available depending on the page displayed. For example, the 'Samples' page provides the ability to hide the two reference samples required for every run.

Samples

– Filter Settings

Filter On: None

Reference Samples: ☒ Omit

Show: All Samples

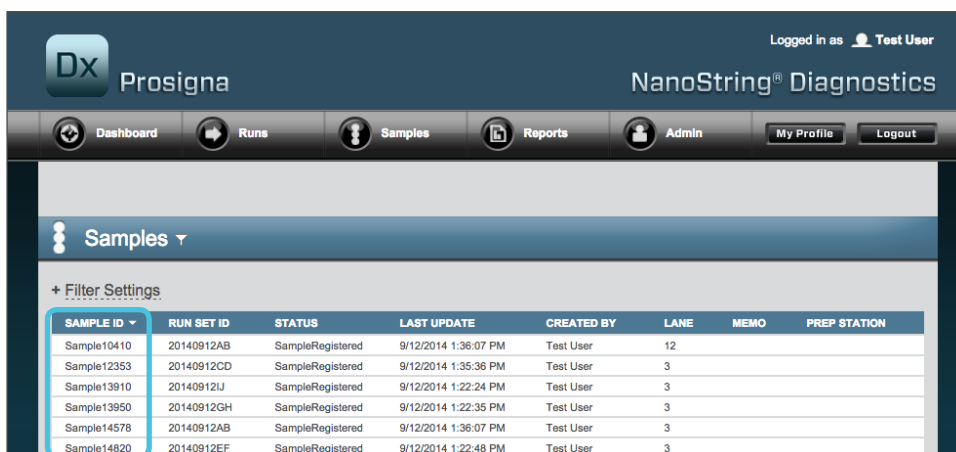
Page Size: 40

Apply

FIGURE 4.11: Check the 'Omit' box to show or hide the reference samples

Sort

All table columns allow users to sort the displayed rows in ascending or descending order. Click on the column heading for the data of interest to sort the rows. To re-sort the data in the reverse order, click again on the same column heading (**FIGURE 4.12**).



Logged in as **Test User**

Dx Prosigna NanoString® Diagnostics

Dashboard Runs Samples Reports Admin My Profile Logout

Samples

+ Filter Settings

SAMPLE ID	RUN SET ID	STATUS	LAST UPDATE	CREATED BY	LANE	MEMO	PREP STATION
Sample10410	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	12		
Sample12353	20140912CD	SampleRegistered	9/12/2014 1:35:36 PM	Test User	3		
Sample13910	20140912UJ	SampleRegistered	9/12/2014 1:22:24 PM	Test User	3		
Sample13950	20140912GH	SampleRegistered	9/12/2014 1:22:35 PM	Test User	3		
Sample14578	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	3		
Sample14820	20140912EF	SampleRegistered	9/12/2014 1:22:48 PM	Test User	3		

FIGURE 4.12: An example of alphabetically sorting samples by clicking on the 'SAMPLE ID' column heading



NOTE: Tables are typically displayed by default with the most recently added items at the top and the oldest items at the bottom.

Forms

Forms are defined in the nCounter web application as pages in which a user can make manual data entry changes. General users with the 'Create Run Set' account privilege have access to the 'Create Run Set' and 'Edit Run Set' forms. Users that lack this privilege may view Run Set and sample statuses, but may not create or edit Run Sets. Administrators may also access other forms, which include:

- **Add new user**
- **Edit user**
- **Date and time**
- **IP address**
- **SSH settings**
- **E-mail configuration**

All forms are designed with the expectation that users complete an action prior to moving to another area within the web application. In order to navigate to another function after completing a form, click **Save** to retain the information entered or **Cancel** to exit the form and discard any changes.

Logged in as **Test User**

Dx Prosigna NanoString® Diagnostics

Dashboard Runs Samples Reports Admin My Profile Logout

Edit Run Set Cancel SAVE RUN SET

1. Assay Type: Prosigna 2. Enter Run Set ID: 20140912CD
Every Run Set ID must be unique. Example: 20120701LB2

3. Test Configuration code: 9+Lkyy59D2x0 4. CodeSet Kit Number: 012345019
Scan or manually enter the barcode labeled 'Run Configuration Code' that came in the CodeSet box Scan or manually enter the Kit Lot Number from the sticker included in the CodeSet box.

5. Enter Sample Data:

WELL #	SAMPLE ID LABEL	# OF POSITIVE NODES	TUMOR SIZE	MEMO
1	Reference1			
2	Reference2			
3	Sample12353	Zero Positive Nodes	<= 2cm	
4	Sample24213	Zero Positive Nodes	> 2cm	
5	Sample32365	1-3 Positive Nodes	<= 2cm	
6	Sample48456	1-3 Positive Nodes	> 2cm	

FIGURE 4.13: The menu bar is inaccessible while editing the contents of a form

C. Dashboard and Status Pages

Dashboard

The Dashboard is the landing page, the first screen displayed after logging into the nCounter web application. The Dashboard can be accessed from other pages by clicking on the **Dashboard** menu item, but it will be unavailable when editing a form until that form has been saved or discarded.

Logged in as **Test User**

Dx Prosigna NanoString® Diagnostics

Dashboard Runs Samples Reports Admin My Profile Logout

COMMON TASKS

- View Run Sets
- Create New Run Set
- Download Reports
- Add New User

Support

- Support Overview
- Contact Support

Ordering and Assay Info

- Order Prosiga Kits

News and Technology Info

- Main Site and News
- Prosiga Website

Logged in as:

Run Sets Show All

RUN SET ID	STATUS	CREATED	CREATED BY	INITIATED BY
20140912U	BatchRegistered	9/12/2014 1:19:40 PM	Test User	
20140912GH	BatchRegistered	9/12/2014 1:18:56 PM	Test User	
20140912EF	BatchRegistered	9/12/2014 1:17:51 PM	Test User	
20140912CD	BatchRegistered	9/12/2014 1:16:52 PM	Test User	
20140912AB	BatchRegistered	9/12/2014 1:13:56 PM	Test User	

Samples Show All

SAMPLE ID	RUN SET ID	STATUS	LAST UPDATE	CREATED BY
Sample14578	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User
Sample27456	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User
Sample34352	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User
Sample48724	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User
Sample52968	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User

Reports Show All

FIGURE 4.14: The Dashboard landing page and the location of the **Dashboard** menu option

The Dashboard provides quick access to the statuses of Run Sets, Samples, and Reports (assuming appropriate privileges have been applied to the user profile). To view the complete status of any of these, click on the **Show All** button shown on the right hand side of the title bar for each.

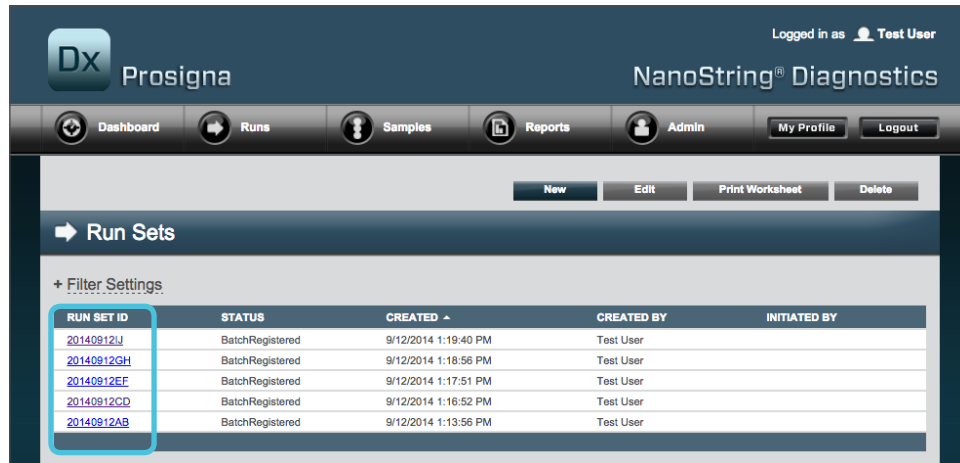
The Dashboard also provides quick access to common tasks located on the left side of the page. Click on the appropriate link to navigate and perform the desired action.

All navigations provided on the Dashboard can be accessed individually by using the menu bar at the top (**FIGURE 4.14**). The Dashboard provides a consolidated view of these to make it easy to perform any function quickly from one place.

Run Set Status

The 'Run Sets' page can be accessed from the Dashboard as described above, and is also available by clicking **Runs** on the menu bar.

The 'Run Sets' page displays the statuses of all Run Sets that have been created.



Logged in as Test User

NanoString® Diagnostics

Dashboard Runs Samples Reports Admin My Profile Logout

New Edit Print Worksheet Delete

Run Sets

+ Filter Settings

RUN SET ID	STATUS	CREATED	CREATED BY	INITIATED BY
20140912IJ	BatchRegistered	9/12/2014 1:19:40 PM	Test User	
20140912GH	BatchRegistered	9/12/2014 1:18:56 PM	Test User	
20140912EF	BatchRegistered	9/12/2014 1:17:51 PM	Test User	
20140912CD	BatchRegistered	9/12/2014 1:16:52 PM	Test User	
20140912AB	BatchRegistered	9/12/2014 1:13:56 PM	Test User	

FIGURE 4.15: Statuses of all Run Sets

The following information is available:

1. **Run Set ID** – The Run Set ID entered when the Run Set was created
2. **Status** – The current condition or state of the Run Set. Status possibilities include:
 - **BatchRegistered** – Run Set Registered (Run Set is defined but has not started processing yet)
 - **PostHybProcessing** – Prep Station Processing (Run Set is currently processing on the Prep Station)
 - **PostHybComplete** – Prep Station Completed (Run Set has completed on the Prep Station)
 - **PostHybAbort** – Prep Station Abort (manual abort on the Prep Station)
 - **PostHybError** – Prep Station Error (an error occurred during processing on the Prep Station)
 - **ScanProcessing** – DA Scan Processing (currently processing on the Digital Analyzer)
 - **ScanError** – DA Scan Error (an error occurred during processing on the Digital Analyzer)
 - **ScanAbort** – DA Scan Abort (manual abort on the Digital Analyzer)
 - **BatchComplete** – Batch Complete (Run Set has completed processing)
 - **ReportPending** – Report Pending (scanning complete, but waiting for the algorithm to complete)
 - **ReportProcessing** – Report Processing (algorithm is running but the report has not been produced yet)
 - **ReportComplete** – Report Complete (Digital Analyzer has finished scanning and reports are available for download from the Reports page)
 - **ReportError** – Report Failed (all processing for the Run Set is complete but a report was not generated due to an error in the algorithm)
 - **ReportCompleteWithError** – Report Complete with Error (all processing for the Run Set is complete, and a report generated, but the assay failed)
3. **Created** – The date the Run Set was initially created using the web application
4. **Created By** – The User ID that created the Run Set using the web application
5. **Initiated By** – The User ID that started processing the Run Set on the Prep Station

To view more details of the individual samples for a Run Set of interest, click on the hyperlink for that Run Set ([FIGURE 4.15](#)). The application will navigate to the 'Samples' page and display sample information for the selected Run Set.

Sample Status

Similar to the 'Run Sets' page, the 'Samples' page can be accessed from the Dashboard and is also available from the **Samples** menu option at the top of the page.

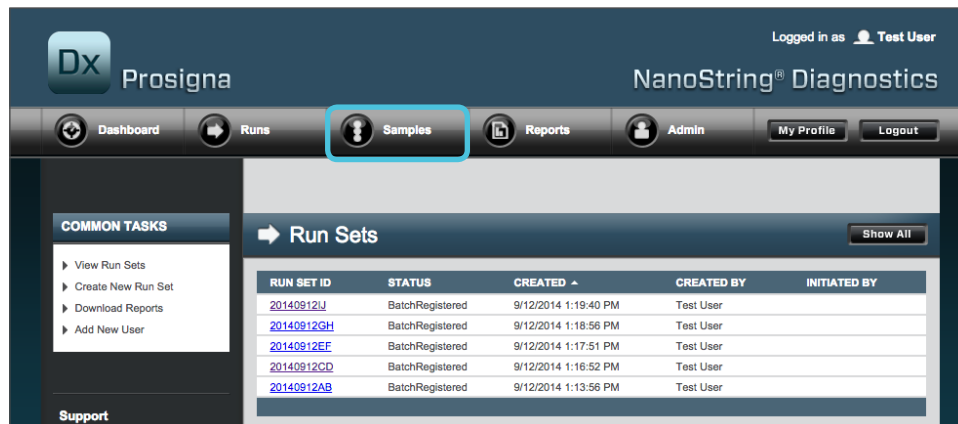


FIGURE 4.16: The location of the 'Samples' menu option

The 'Samples' page allows users to view the statuses of all samples for all Run Sets.

The screenshot shows the 'Samples' page in the NanoString Diagnostics web application. The top navigation bar is the same as in Figure 4.16. The main content area displays the 'Samples' table with columns for Sample ID, Run Set ID, Status, Last Update, Created By, Lane, Memo, and Prep Station. The table lists 12 samples, all with a status of 'SampleRegistered' and created by 'Test User'.

SAMPLE ID	RUN SET ID	STATUS	LAST UPDATE	CREATED BY	LANE	MEMO	PREP STATION
Sample14578	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	3		
Sample27456	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	4		
Sample34352	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	5		
Sample48724	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	6		
Sample52968	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	7		
Sample65702	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	8		
Sample72306	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	9		
Sample82380	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	10		
Sample91306	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	11		
Sample10410	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	12		

FIGURE 4.17: The statuses of all samples contained within all Run Sets

The following information is available:

1. **Sample ID** – The Sample ID entered manually or via a barcode scanner when creating the Run Set
2. **Run Set ID** – The Run Set ID entered when creating the Run Set in the web application
3. **Status** – The condition or state that the sample is currently in. The following are possible statuses for a sample:
 - **SampleRegistered** – Sample Registered (Sample is defined; has not started processing yet)
 - **PostHybProcessing** – Prep Station Processing (Run Set is currently processing on the Prep Station)
 - **PostHybComplete** – Prep Station Completed (Run Set has completed on the Prep Station)
 - **PostHybAbort** – Prep Station Abort (manual abort on the Prep Station)
 - **PostHybError** – Prep Station Error (an error occurred during processing on the Prep Station)
 - **ScanProcessing** – DA Scan Processing (currently processing on the Digital Analyzer)
 - **ScanError** – DA Scan Error (an error occurred during processing on the Digital Analyzer)
 - **ScanAbort** – DA Scan Abort (manual abort on the Digital Analyzer)
 - **ReportPending** – Report Pending (Scanning complete, but waiting for the algorithm to complete)
 - **ReportProcessing** – Report Processing (Algorithm is running but the report has not been produced yet)
 - **ReportComplete** – Report Complete (Digital Analyzer has finished scanning and reports are available for download from the Reports page)
 - **ReportError** – Report Failed (All processing for the run set is complete but a report was not generated due to an error in the algorithm)
 - **ReportCompleteWithError** – Report Complete with Error (All processing for the run set is complete, and a report generated, but the assay failed)
4. **Last Update** – The date that the sample last changed status
5. **Created By** – The User ID that created the Run Set using the web application
6. **Lane** – The lane where the sample resides on the cartridge
7. **Memo** (optional) – Notes about the sample entered in the Memo field of the Run Set form.
8. **Prep Station** – Name of the Prep Station on which the sample was processed, useful if more than one Prep Station is connected to the Digital Analyzer

D. Run Sets

This section guides users through creating, editing, printing, and deleting Run Sets.

Create a Run Set

Users are required to create a Run Set associating the sample IDs with their strip tube well locations using the nCounter web application.

A user can choose to create a new Run Set from several places within the web application. The most common way is to select the option **Runs** from the menu bar at the top of the page and choose **Create New Run Set** from the sub-menu that appears below ([FIGURE 4.18](#)).

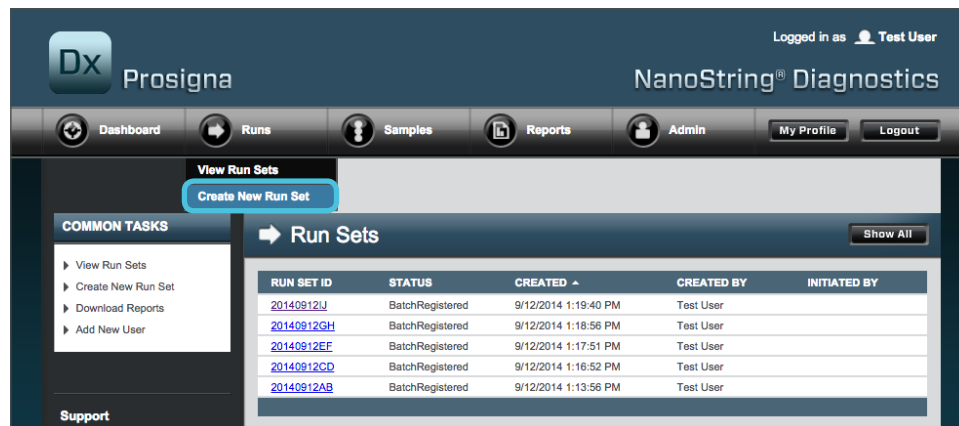


FIGURE 4.18: The **Create New Run Set** option is in the **Runs** sub-menu

>>> The 'Create New Run Set' form will appear.

The screenshot shows the 'Create New Run Set' form. It includes fields for 'Assay Type' (Prosigna), 'Enter Run Set ID' (20140912AB), 'Test Configuration code' (wL28s0++w14), and 'CodeSet Kit Number' (012345019). Below these fields is a table for 'Enter Sample Data' with columns for Well #, Sample ID Label, # of Positive Nodes, Tumor Size, and Memo.

WELL #	SAMPLE ID LABEL	# OF POSITIVE NODES	TUMOR SIZE	MEMO
1	Reference1			
2	Reference2			
3	Sample1	Zero Positive Nodes	<= 2cm	
4	Sample2	Zero Positive Nodes	<= 2cm	
5	Sample3	1-3 Positive Nodes	> 2cm	
6	Sample4	Zero Positive Nodes	> 2cm	
7	Sample5	Zero Positive Nodes	> 2cm	
8	Sample6	1-3 Positive Nodes	<= 2cm	
9	Sample7	Zero Positive Nodes	<= 2cm	
10	Sample8	1-3 Positive Nodes	> 2cm	
11	Sample9	Zero Positive Nodes	<= 2cm	
12	Sample10	Zero Positive Nodes	<= 2cm	

FIGURE 4.19: The 'Create New Run Set' form

Enter the following information to create a Run Set:

1. **nCounter Assay Type** – The nCounter assay type was previously selected during sign in (FIGURE 4.1). To change this entry, log out and sign in again while selecting a new assay type.
2. **Run Set ID** – The Run Set ID must provide a unique name to identify the Run Set.
3. **Test Configuration Code** – The Test Configuration Code is an alphanumeric barcode located inside the CodeSet box. It determines the number of samples that can be processed.
4. **CodeSet Kit Number** – The CodeSet Kit Number is a numeric barcode located inside the CodeSet box and is also described as a CodeSet Barcode Sticker. It determines the CodeSet expiration date. Because there may be a delay between creating a Run Set and processing the samples, a warning will be provided if the CodeSet is within two weeks of its expiration date when the Run Set is created.
5. **Sample Data** – The reference samples are always located in wells 1 and 2; they do not require any input and cannot be edited. Well numbers 3-12 are used for patient RNA samples. Fields may vary for different assay types. As an example, Prosigna requires the following information:
 - a. **Sample ID Label** (required) – Sample IDs can be entered using barcoded sample tubes and a barcode scanner connected to the computer. If a scanner is not available or if the barcodes are damaged, sample IDs can be manually entered using a keyboard. NanoString recommends using unique sample IDs to track samples.
 - b. **# of Positive Nodes** (required) – Users can choose between zero positive nodes, 1-3 positive nodes or ≥ 4 positive nodes (where available).
 - c. **Tumor Size** (required) – Users can choose between ≤ 2 cm or > 2 cm.
 - d. **Memo** (optional) – Any notes about the sample can be entered here. There is a maximum limit of 32 characters.



NOTE: Leave the remaining fields blank if any strip tube wells are not needed. If additional fields are required for more samples, use a different test configuration that accommodates more samples.



IMPORTANT: Some handheld scanners can misinterpret barcodes if they are not properly configured. It is essential that the Test Configuration Code and CodeSet Kit Number be entered correctly. If you encounter errors, contact dxsupport@nanosttring.com for assistance.

6. **Set E-mail Recipients** – If desired, choose e-mail recipients by selecting users from the contact list on the left side and clicking the **Add>>** button. Conversely, e-mail recipients can be removed by selecting the users from the list on the right side and clicking the **<<Remove** button. Press the **Ctrl** key (or the **Command** key if using an Apple computer) on the keyboard while selecting multiple addresses to add or remove multiple recipients at once.
 - a. **E-mail Status Updates to** – Users assigned here will receive e-mail updates anytime the Run Set status has changed.
 - b. **E-mail Report Notifications to** – Users assigned here will receive an e-mail when the sample reports for the Run Set are available for download. E-mails will include a link to log in and download the appropriate nCounter reports.



NOTE: A user must have proper permissions set in their user profile in order to be able to receive e-mail report notifications. Attempts to assign a user without appropriate access to receive report notifications will result in an error message. To change these permissions, an administrator must edit the user's profile and add the privilege.

The screenshot shows the 'Create New Run Set' form. At the top is a table with 5 columns: WELL #, SAMPLE ID LABEL, # OF POSITIVE NODES, TUMOR SIZE, and MEMO. The table contains 12 rows of data. Below the table is a section titled '6. Set E-mail Recipients:'. This section contains a 'CONTACT LIST' with a list of names (Administrator, Alpha, Beta, Charlie, David, Elena, Frank, Gamma, Helen, Karen, Test User) and two buttons: 'Add >>' and '<< Remove'. To the right of the contact list are two sections: 'E-mail STATUS UPDATES to:' and 'E-mail REPORT NOTIFICATIONS to:', both with a text input field containing 'Test User' and the same 'Add >>' and '<< Remove' buttons. At the bottom right of the form are 'Cancel' and 'SAVE RUN SET' buttons.

WELL #	SAMPLE ID LABEL	# OF POSITIVE NODES	TUMOR SIZE	MEMO
1	Reference1			
2	Reference2			
3	Sample1	Zero Positive Nodes	<= 2cm	
4	Sample2	Zero Positive Nodes	<= 2cm	
5	Sample3	1-3 Positive Nodes	> 2cm	
6	Sample4	Zero Positive Nodes	> 2cm	
7	Sample5	Zero Positive Nodes	> 2cm	
8	Sample6	1-3 Positive Nodes	<= 2cm	
9	Sample7	Zero Positive Nodes	<= 2cm	
10	Sample8	1-3 Positive Nodes	> 2cm	
11	Sample9	Zero Positive Nodes	<= 2cm	
12	Sample10	Zero Positive Nodes	<= 2cm	

FIGURE 4.20: The location of the contact list and email alerts on the 'Create New Run Set' form

It is crucial that sample information is entered correctly. Each well must be completed with all required information before sample information is entered for the next well. When all information for the Run Set has been entered, click on **Save Run Set**. After the Run Set has been saved, a prompt to print a worksheet will appear.

The screenshot shows a 'Print Worksheet' dialog box. It has a red person icon at the top left. The text reads: 'Print Worksheet', 'Do you want to print the worksheet for the current run set?'. At the bottom are 'Cancel' and 'OK' buttons.

FIGURE 4.21: The 'Print Worksheet' prompt

Select **OK** to print the Run Set Worksheet.



NOTE: Clicking the **Cancel** button will navigate the user to the Run Sets page.



NOTE: The Run Set will still be saved in the application if a worksheet is not printed, but it is recommended that a printed worksheet be used in the laboratory when preparing samples. The worksheet may also be printed at a later date.

>>>The worksheet will appear in a new window (**FIGURE 4.22**).

Run Set ID: 20140912AB		CodeSet Kit Number: 0123450199		
Assay: Prosigna		RNA Isolation Kit Lot:		
Date / Time: 9/12/2014 1:14 PM		Email Status Updates: Test User		
Created By: Test User		Email Report Notifications: Test User		

Well #	Sample ID Label	# of Positive Nodes	Tumor Size	Memo
1	Reference1	N/A	N/A	N/A
2	Reference2	N/A	N/A	N/A
3	Sample1	Zero Positive Nodes	<= 2cm	
4	Sample2	Zero Positive Nodes	<= 2cm	
5	Sample3	1-3 Positive Nodes	> 2cm	
6	Sample4	Zero Positive Nodes	> 2cm	
7	Sample5	Zero Positive Nodes	> 2cm	
8	Sample6	1-3 Positive Nodes	<= 2cm	
9	Sample7	Zero Positive Nodes	<= 2cm	
10	Sample8	1-3 Positive Nodes	> 2cm	
11	Sample9	Zero Positive Nodes	<= 2cm	
12	Sample10	Zero Positive Nodes	<= 2cm	

[Close](#) [Print](#)

FIGURE 4.22: An example worksheet

Select **Print** to print the worksheet, and then close the worksheet. The application will return to the Run Sets page.

Edit a Run Set

Run Sets with the status 'BatchRegistered' can be edited. Users should edit a Run Set to match the final hybridization record if sample information was altered. For example, the Sample ID Labels may be updated if patient samples are swapped out or if a new sample ID is assigned.

To edit a Run Set, select the appropriate Run Set from the list on the 'Run Sets' page and click the Edit button (FIGURE 4.23).

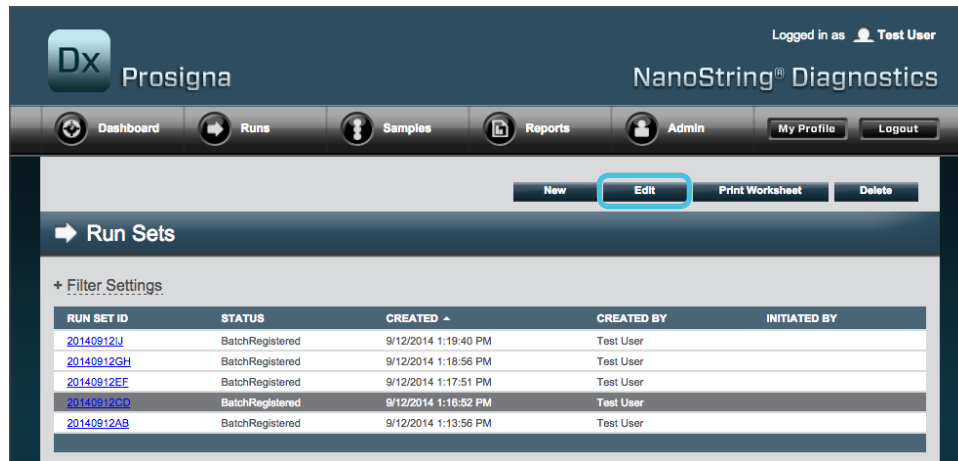


FIGURE 4.23: Location of the **Edit** button on the 'Run Sets' page

>>> The 'Edit Run Set' page will appear.

1. Assay Type: Prosigna

2. Enter Run Set ID: 20140912CD
Every Run Set ID must be unique. Example: 20120701LB2

3. Test Configuration code: 9+Lkyy59D2x0
Scan or manually enter the barcode labeled 'Run Configuration Code' that came in the CodeSet box

4. CodeSet Kit Number: 012345019
Scan or manually enter the Kit Lot Number from the sticker included in the CodeSet box.

5. Enter Sample Data:

WELL #	SAMPLE ID LABEL	# OF POSITIVE NODES	TUMOR SIZE	MEMO
1	Reference1			
2	Reference2			
3	Sample12353	Zero Positive Nodes	<= 2cm	
4	Sample24213	Zero Positive Nodes	> 2cm	
5	Sample32365	1-3 Positive Nodes	<= 2cm	
6	Sample48456	1-3 Positive Nodes	> 2cm	

FIGURE 4.24: The 'Edit Run Set' page



NOTE: Clicking on the Run Set ID hyperlink will NOT open the Run Set for editing. Clicking the hyperlink will open the 'Samples' status page, pre-filtered to view only that Run Set.

Verify that the correct Run Set has been opened, and then edit the Run Set as needed. Save changes by clicking the **Save Run Set** button at the top. When prompted, print the worksheet as recommended earlier in this section.

Delete a Run Set

Run Sets with the status 'BatchRegistered' can be deleted if necessary. To delete a Run Set, select the appropriate Run Set from the list and click the **Delete** button (FIGURE 4.25).

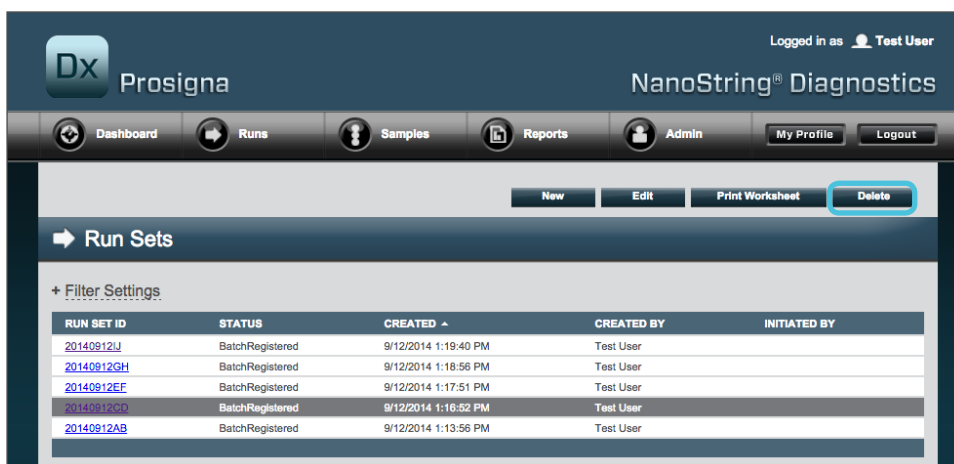


FIGURE 4.25: Location of the **Delete** button on the 'Run Sets' page

>>> A prompt will appear to confirm deletion of the Run Set.

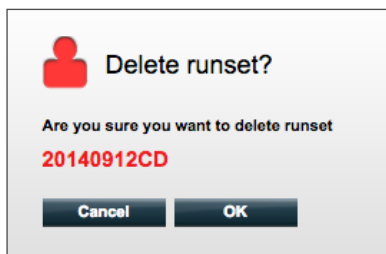


FIGURE 4.26: The 'Delete runset?' prompt

Click **OK** to delete the Run Set or **Cancel** to return to the 'Run Sets' page.

E. Print Worksheets

It is highly recommended that worksheets be used when setting up hybridization reactions. As described earlier, when a Run Set is saved the system will prompt the user to print the worksheet. However, it is also possible to print Run Set worksheets at any time from the nCounter web application.

To print a Run Set worksheet, navigate to the 'Run Sets' page, select the Run Set row of interest, and click the **Print Worksheet** button (FIGURE 4.27).

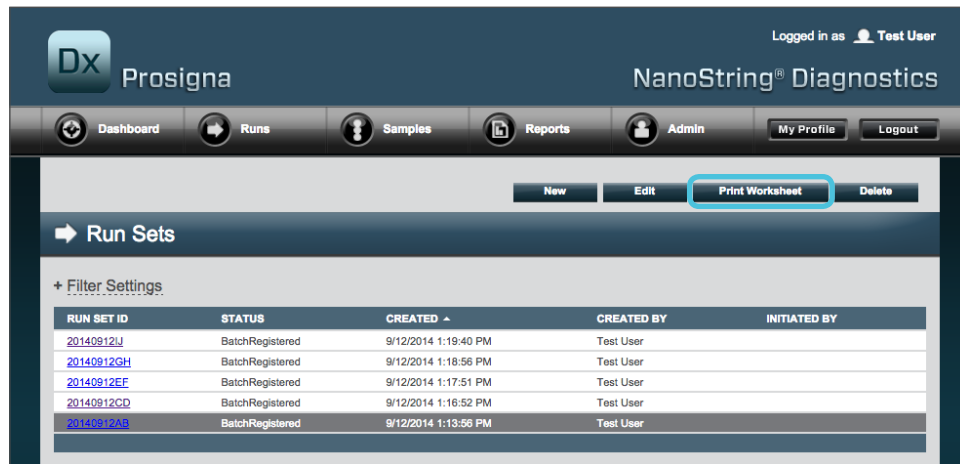


FIGURE 4.27: Location of the **Print Worksheet** button on the 'Run Sets' page

>>> The worksheet will appear in a new window.

Run Set ID: 20140912AB		CodeSet Kit Number: 0123450199		
Assay: Prosigna		RNA Isolation Kit Lot:		
Date / Time: 9/12/2014 1:49 PM		Email Status Updates: Test User		
Created By: Test User		Email Report Notifications: Test User		
Well #	Sample ID Label	# of Positive Nodes	Tumor Size	Memo
1	Reference1	N/A	N/A	N/A
2	Reference2	N/A	N/A	N/A
3	Sample14578	Zero Positive Nodes	<= 2cm	
4	Sample27456	Zero Positive Nodes	<= 2cm	
5	Sample34352	1-3 Positive Nodes	> 2cm	
6	Sample48724	Zero Positive Nodes	> 2cm	
7	Sample52968	Zero Positive Nodes	> 2cm	
8	Sample65702	1-3 Positive Nodes	<= 2cm	
9	Sample72306	Zero Positive Nodes	<= 2cm	
10	Sample82380	1-3 Positive Nodes	> 2cm	
11	Sample91306	Zero Positive Nodes	<= 2cm	
12	Sample10410	Zero Positive Nodes	<= 2cm	

[Close](#) [Print](#)

FIGURE 4.28: An example worksheet

Click the **Print** button to begin the printing process for the worksheet or the **Close** button to close the window.

F. Reports

Users with the 'Access Diagnostic Reports' privilege can select and download diagnostic reports from the Reports page.

Users chosen to receive a report notification when setting up the Run Set should receive an e-mail stating that the sample processing is complete and that the report is available for download. A link to download reports from the web application is included within the e-mail notification.



NOTE: The download link requires the user to log in to the nCounter web application before diagnostic reports can be accessed.

From the Reports page, select the row(s) of the samples to be downloaded and click the **Download** button (FIGURE 4.29).

SAMPLE ID	RUN SET ID	REPORT DATE	CREATED BY	ASSAY STATUS
Reference1	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Reference2	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample1	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample2	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample3	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample4	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample5	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample6	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample7	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample8	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample9	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample10	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete

FIGURE 4.29: The 'Reports' page

The reports will be compressed into a ZIP file (*.zip). This file can be opened immediately or saved to a specified location on a computer or network.



NOTE: Remember that reports contain confidential information. Be careful when saving to a network or location that may be accessed by others.

G. Administration

For users designated with the Administrative role, the **Admin** button is available in the top menu bar of the web application. Administrators can choose from three main functions:

- **Manage Users**
- **System Settings**
- **Add User**

Add, Delete, and Manage Users

To add a new user, select **Admin** from the top menu bar and click on **Add User**.

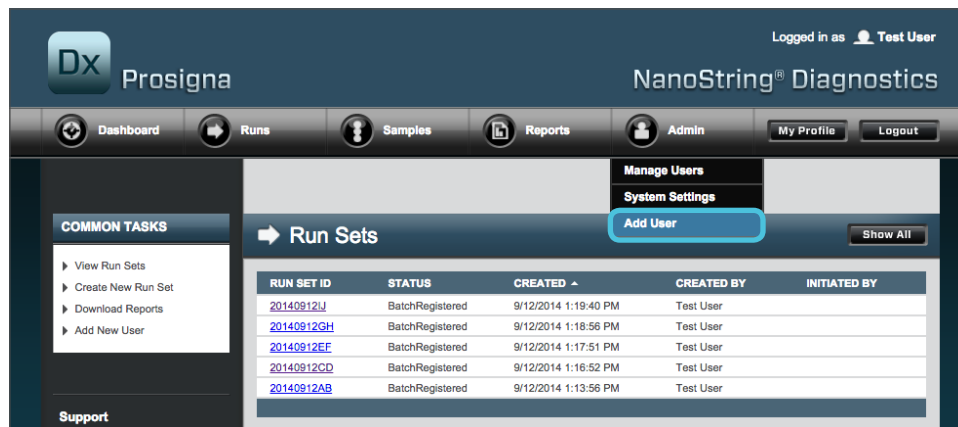


FIGURE 4.30: The location of the **Add User** button in the **Admin** sub-menu

>>> The 'Add New User' form will appear.

The screenshot shows the 'Add New User' form. It includes fields for USER ID, PASSWORD, CONFIRM PASSWORD, and E-MAIL ADDRESS. Below these fields are radio buttons for USER TYPE: Administrator (selected) and General (no admin privileges). Under PERMISSIONS, there are checkboxes for RUN POST HYBRIDIZATION, ACCESS REPORTS, and CREATE RUN SET, each with sub-options for Prosigna and Assay 2. At the bottom are 'Cancel' and 'Save' buttons.

FIGURE 4.31: The 'Add New User' form

Enter the following information and click the **Save** button.

- **User ID** (required)
- **Password** (required)
- **Confirm Password** (required)
- **E-mail address** (required)
- **User type** (required) – choose either:
 - **General** – Access to standard functionality including creating a Run Set (access does not include processing samples)
 - **Administrator** – General user access plus administrative access including user management and system settings
- **Permissions** (at least one permission is required) – choose all that apply:
 - **Run Post Hybridization** – This permission is required to operate the Prep Station and initiate the post hybridization process for the assay(s) selected
 - **Access Reports** – This permission is required to view the Reports tab on the Web Application and download diagnostic reports for the assay(s) selected
 - **Create Run Set** – This permission is required to create a new Run Set or edit an existing Run Set on the Web Application for the assay(s) selected



NOTE: Administrators do not automatically have permission to access diagnostic reports and initiate post hybridization processing on the Prep Station; permission must still be assigned. Administrators are able to assign permissions to their own accounts.



NOTE: Unique permission settings can be assigned for each assay type available on the system. For example, a user may be able to create a Run Set for all assays on their system, initiate post hybridization for a single assay, and be unable to access any reports.

The Manage Users function allows an administrator to edit or delete users. To manage existing users, select the **Admin** option from the menu bar at the top of the page and click on **Manage Users**.

>>> The 'Manage Users' screen will appear.

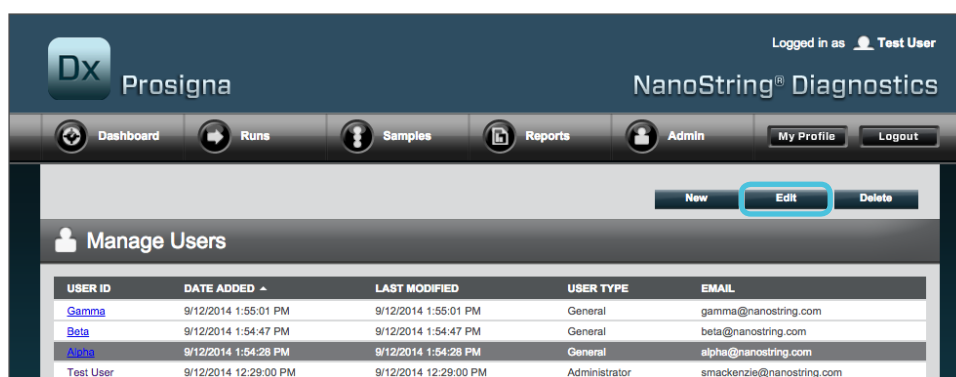


FIGURE 4.32: The 'Manage Users' page and the location of the **Edit** button

To edit a user, select the User ID link or select the row for the specified user and click the **Edit** button.

>>> The 'Edit User Data' form will appear.

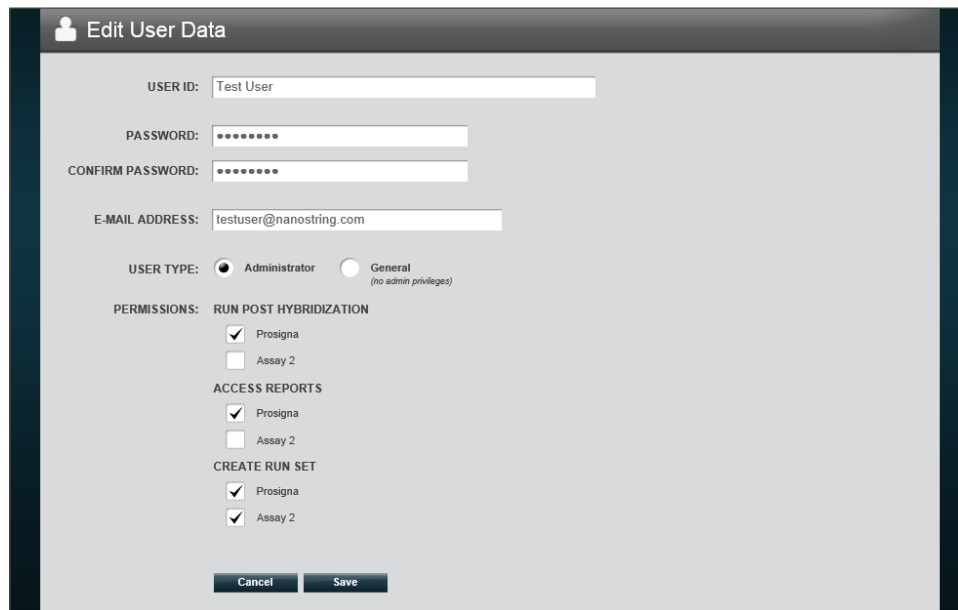


FIGURE 4.33: The 'Edit User Data' form

Edit any of the following information and click the **Save** button to save any changes made.

- **User ID**
- **Password**
- **Confirm Password**
- **E-mail Address**
- **User Type**
- **Assay Permissions**
 - **Run Post Hybridization**
 - **Access Reports**
 - **Create Run Set**

To delete a user, open the 'Manage Users' page, select the row for the appropriate user, and click the **Delete** button (FIGURE 4.34).

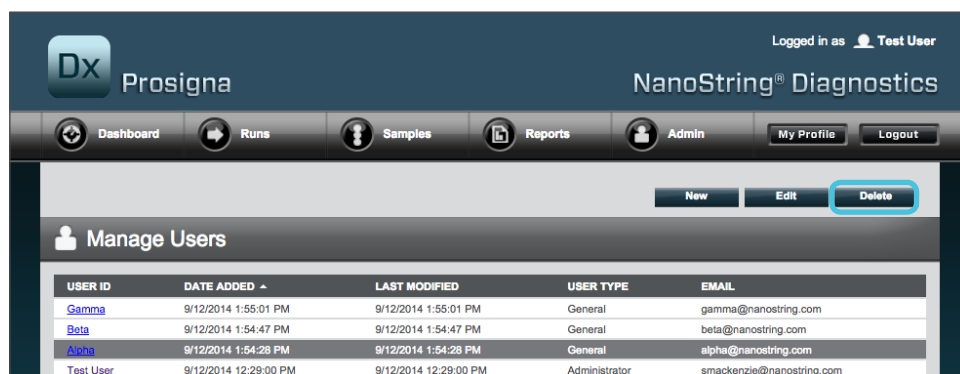


FIGURE 4.34: Location of the **Delete** button on the 'Manage Users' page

>>> A confirmation message will appear.

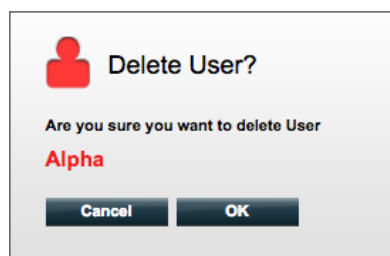


FIGURE 4.35: The 'Delete User?' prompt

Click **OK** to delete the user or click **Cancel** to return to the 'Manage Users' page.

System Settings

System settings are available to users with the Administrative user type. There are four main functions within the 'System Settings' page:

- **Date and Time**
- **E-mail Settings**
- **SSH Settings**
- **IP Address**

To access the 'System Settings' page, select the **Admin** option on the top menu bar and select **System Settings** (FIGURE 4.36).

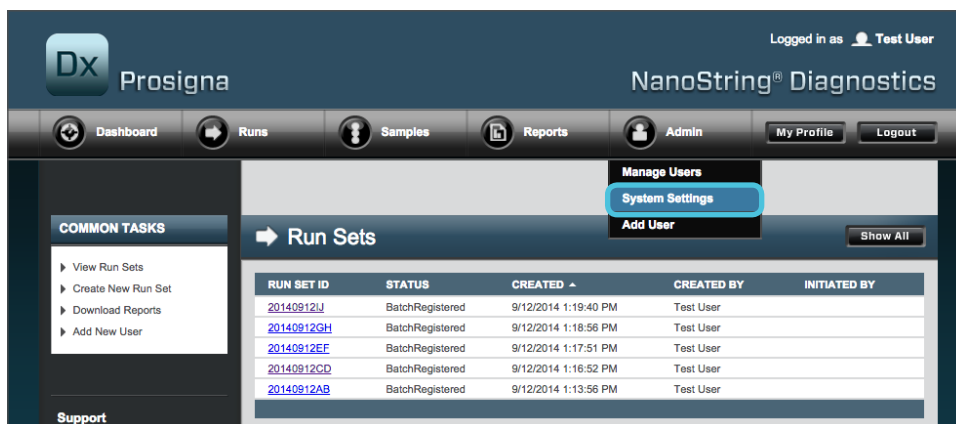


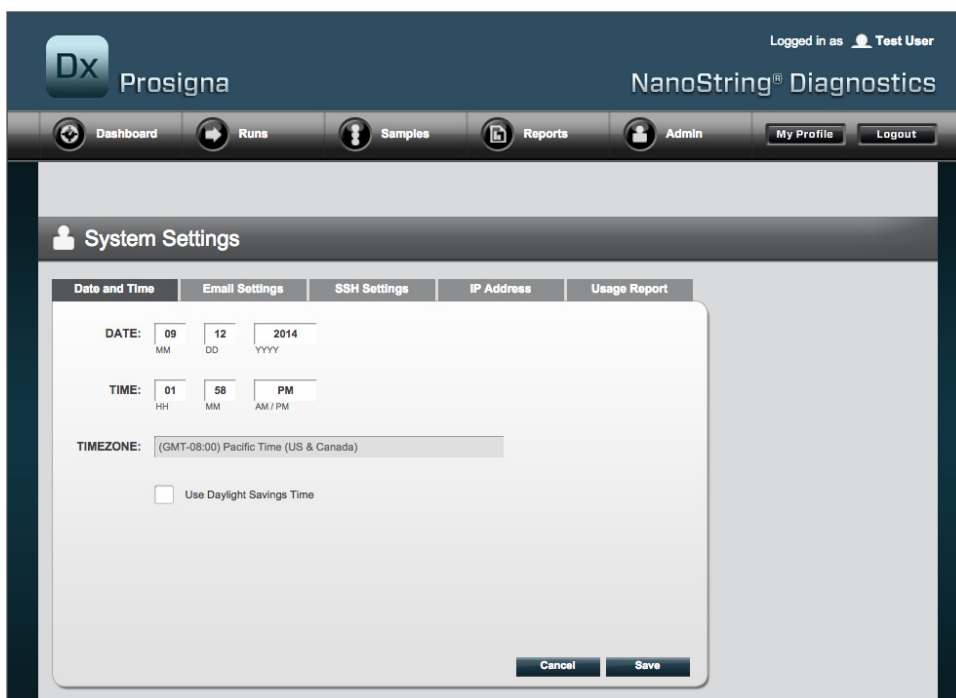
FIGURE 4.36: Location of the **System Settings** option in the **Admin** sub-menu

>>> The 'System Settings' page will appear (FIGURE 4.37).

The four different functions described above are organized in different tabs. The default tab displayed is 'Date and Time'.

Date and Time

Date and time settings are initially set when NanoString personnel set up the nCounter. Change these settings only when necessary. Click **Save** to save any changes or **Cancel** to discard changes and perform another function.



The screenshot displays the 'System Settings' page with the 'Date and Time' tab selected. The page header includes the 'Dx Prosigna' logo, 'NanoString® Diagnostics' text, and a 'Logged in as Test User' status. The navigation bar contains links for Dashboard, Runs, Samples, Reports, Admin, My Profile, and Logout. The 'Date and Time' tab is active, showing input fields for Date (09/12/2014), Time (01:58 PM), and Timezone (GMT-08:00 Pacific Time (US & Canada)). A checkbox for 'Use Daylight Savings Time' is present and unchecked. 'Cancel' and 'Save' buttons are at the bottom of the form.

FIGURE 4.37: The 'Date and Time' tab on the 'System Settings' page



NOTE: Administrators cannot adjust the Time Zone or Daylight Saving Time options. Contact NanoString Support if these values need to be adjusted.



NOTE: Changing the date and/or time in the nCounter web application adjusts these values on the Digital Analyzer and Prep Station, as well. Take care when making changes to these settings.

E-mail Settings

E-mail settings must be configured in order for the nCounter system to successfully send automated e-mails for status updates such as Prep Station run completion or diagnostic report notifications.

The screenshot displays the 'System Settings' window in the NanoString Diagnostics application. The 'Email Settings' tab is active, showing the following configuration details:

- SMTP SERVER:** 10092.outlook.com
- SMTP PORT:** 587
- FROM ADDRESS:** xSystem@nanosttring.com
- Enable SSL:** ☒
- SMTP USERNAME:** xSystem@nanosttring.com
- PASSWORD:** [masked]
- CONFIRM PASSWORD:** [masked]
- ENCRYPTION PROTOCOL:** SSL3
- TEST ADDRESS:** [empty field]

Buttons for 'Test', 'Cancel', and 'Save' are located at the bottom of the form.

FIGURE 4.38: The 'E-mail Settings' tab

The following fields are available:

- **SMTP Server** (required) – (Simple Mail Transfer Protocol) – E-mail server name
- **SMTP Port** (required) – Port used for e-mail server
- **SMTP Address** (required) – Address from which automated e-mails are sent
- **Enable SSL** – Check if using a secure e-mail server
- **SMTP Username** – Account name for secure e-mail server (required if **Enable SSL** is checked)
- **Password** – Password for SMTP username (required if **Enable SSL** is checked)
- **Confirm Password** – Same password as above (required if **Enable SSL** is checked)
- **Encryption Protocol** – These options effectively encrypt e-mail data sent over the Internet between the client and e-mail server. The following are possible values for encryption protocol (a selection is required if **Enable SSL** is checked):
 - **SSL3 (Secure Socket Layer)** – Widely used encryption protocol
 - **TLS (Transport Layer Security)** – More secure encryption protocol than SSL
- **Test Address** (optional) – This can be used to test if the e-mail settings are configured correctly. Enter an e-mail address you have access to and press the Test button. Check your e-mail account to confirm that the settings are working and the test e-mail was received.

SSH Settings

The 'SSH Settings' tab allows an Administrator to configure the Secure Shell server (SSH server). The SSH server allows users to programmatically pull nCounter report data from the system in a secure manner. It also allows for unlimited concurrent client connections.

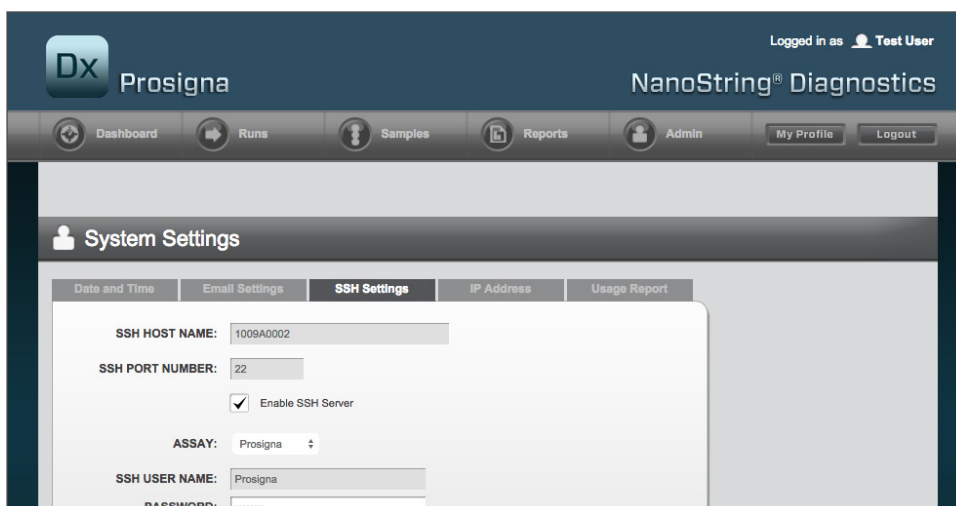


FIGURE 4.39: The 'SSH Settings' tab

The following fields are available:

Pre-configured fields

- **SSH host name** – The name of the host used by the client for connecting to the SSH server
- **SSH port number** – The port used by the client for connection to the SSH server
- **SSH user name** – SSH server account name used by the client for authenticating the connection

Configurable fields

- **Enable SSH server** – Check box for enabling or disabling the SSH server.
- **Password** – SSH server account password used by the client for authenticating the connection (required when 'enable SSH server' is checked)
- **Confirm Password** – Same password entered as above (required when enable SSH server is checked)

IP Address

IP address function is an essential function to enable networking of the instruments. The Prep Station, Digital Analyzer, and nCounter web application are all in frequent communication. The IP address is the basis for setting up this communication. Avoid errors when making changes to the 'IP Address' settings.

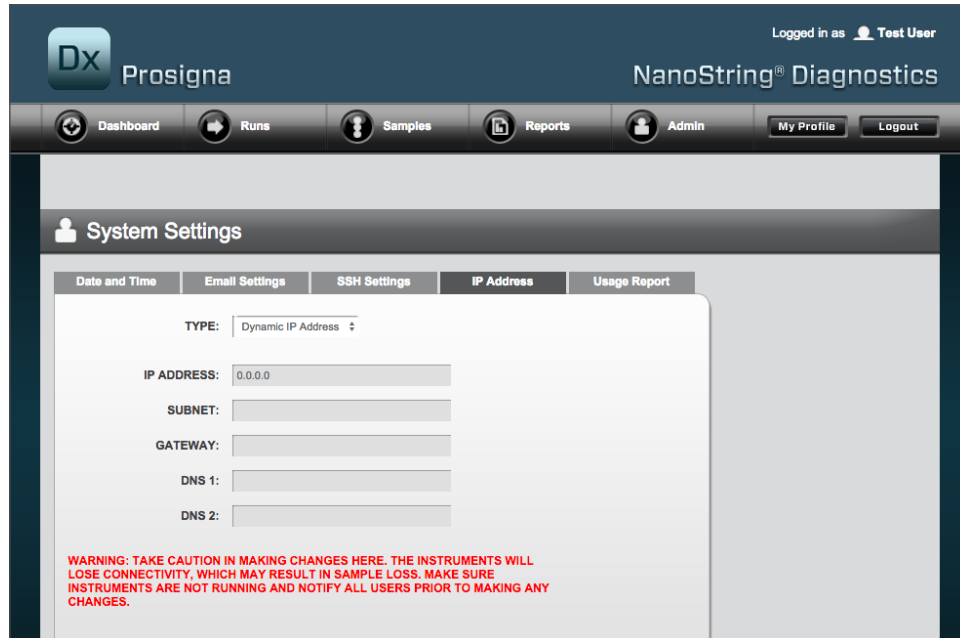


FIGURE 4.40: The 'IP Address' tab

The following fields are available:

- **Type** – The following options are available to choose between:
 - **Static IP address** – This requires the network administrator to set an address that will never change.
 - **Dynamic IP address** (default) – Known as DHCP, this option allows the local network to automatically find and assign an IP address. This address is subject to change.
- **IP Address** – IP address provided by the network administrator (for Static IP address)
- **Subnet** – Subnet provided by the network administrator (for Static IP address)
- **Gateway** – Gateway address provided by the network administrator (for Static IP address)
- **DNS 1** – Domain Name Server provided by the network administrator (for Static IP address)
- **DNS 2** – A second DNS is optionally provided by the network administrator and used as a backup (for Static IP address)



NOTE: A Static IP Address is particularly useful because it ensures more reliable communication between the Digital Analyzer and the Prep Station. If the **Dynamic IP Address** option is chosen, the Digital Analyzer may sometimes acquire a different IP address, giving rise to the possibility of intermittent communication issues.

5 Operating the Prep Station

A. Prior to Initiating a Run

Waste Removal

Prior to starting a new run, ensure that the waste containers have been emptied. Empty waste containers are required for every run.



CAUTION: If waste containers are not emptied, tips could come into contact with waste liquids and contaminate samples, or excess tips could pile up and cause a system malfunction.



CAUTION: Used plastic ware such as reagents, cartridges, and pipetting tips must be collected and disposed of properly in accordance with local safety regulations and laboratory procedures.

1. Remove the combined waste receptacle by lifting it straight up and out of the Prep Station.
2. Remove the liquid waste container from the combined receptacle by using the latch on the front and dispose of the liquid appropriately.
 - Tips should be discarded into the appropriate waste receptacle as outlined in the local organization's laboratory procedures.
 - If biohazardous samples are not being used in the system – and if permitted by the laboratory procedures – liquid waste may be disposed of in the sink or other drain.
3. Verify that the plastic rack holding the used piercers, tip sheaths, reagent plates, and strip tubes from the previous run have all been removed from the deck.

Consumables Required

The consumables required for each run are available as part of the test kit. The kit contains the reagents and consumables required to process 1, 2, 3, 4, 10, 20, 30, or 40 patient samples.

The components of a test kit required to operate the Prep Station include:

- CodeSet Barcode (included inside CodeSet box)
- Sample Cartridges
- Reagent Plates
- Pipette Tips
- Tip Sheaths
- 12-Tube Strips and Caps
- Cartridge Adhesive Covers

B. Initiating a Run

The following steps summarize the workflow beginning from the Welcome screen on the Prep Station touchscreen.

1. To process samples using the Prep Station, a user must log on to the instrument. In order to log on, touch **Main Menu** on the Welcome Screen.

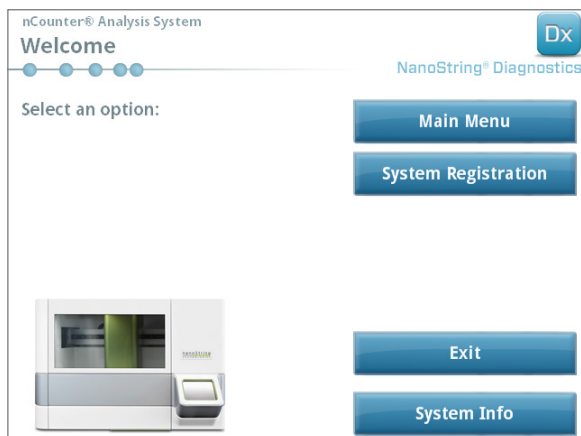


FIGURE 5.1: The Prep Station 'Welcome' screen

2. Enter a valid user name and password and touch **Sign In**.



FIGURE 5.2: The sign in screen

>>> The Main Menu will appear (**FIGURE 5.3**)

3. To set up a new run, touch **Process Samples** from the Main Menu.

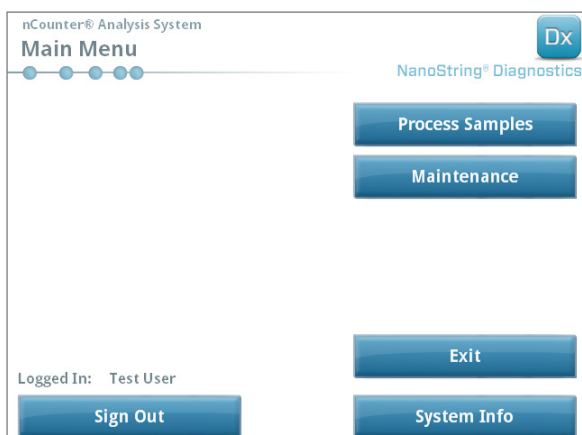


FIGURE 5.3: The Prep Station Main Menu

>>> The 'Process A Run Set' screen will appear.

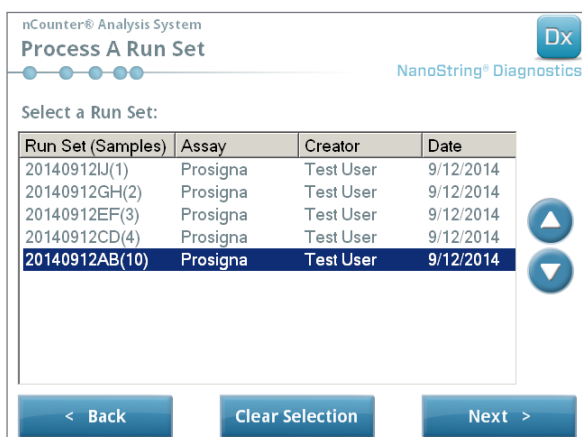


FIGURE 5.4: The 'Process a Run Set' screen displays the name of each Run Set, the assay type, and the number of samples it contains.



NOTE: The **Exit** button will only appear on the Welcome screen and Main Menu if the user has the nCounter Dx Analysis System with FLEX configuration (see *Chapter 3 – Selecting the Instrument Mode*).

4. Select the Run Set to be processed by touching the Run Set name. Use the arrow keys on the right side of the screen to scroll through the selections. Touch **Next** to continue.

>>> The 'Review Reaction Layout' screen will appear.

Name	Value
Sample ID	Sample72306
Comment	
# of Positive Nodes	Zero Positive Nodes
Tumor Size	<= 2cm

Navigation buttons: < Back, Cancel, Next >

FIGURE 5.5: The 'Review Reaction Layout' screen with two reference samples (yellow) and 10 patient samples (blue). One patient sample is selected (green).

5. Touch individual samples to view their details. Verify that the Run Set and sample information are correct (FIGURE 5.5). If not, return to the web application and make the appropriate corrections. (First touch **Cancel** on the Prep Station to make them available for editing.) If they are correct, touch **Next**.

>>> The 'Scan CodeSet' screen will appear.

Barcode: 0123450199

Manual Entry

Navigation buttons: < Back, Cancel, Next >

FIGURE 5.6: The 'Scan CodeSet' screen

6. The barcode for the CodeSet must be scanned before proceeding. Hold the barcode of the CodeSet in front of the barcode reader. A red beam will appear. Move the barcode in front of the red beam until it is read. When the barcode is successfully entered, the barcode number will appear in the box (FIGURE 5.6).



NOTE: The CodeSet barcode must match the CodeSet Kit Number entered when the Run Set was created using the web application (FIGURE 4.19).

>>> The 'Reagents And Cartridge' screen will appear.

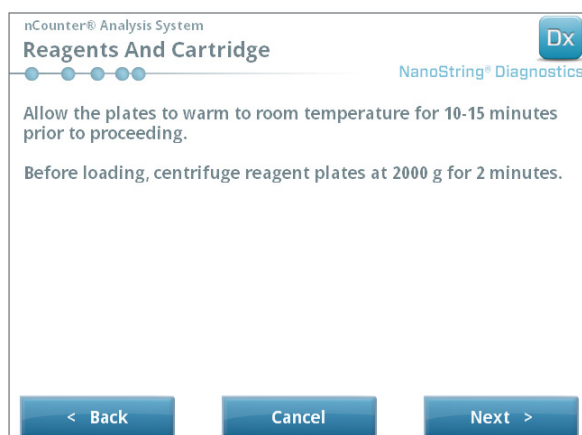


FIGURE 5.7: The 'Reagents And Cartridge' screen

7. Cartridges and reagent plates (FIGURE 5.8) must be at room temperature prior to processing.
 - a. Remove the nCounter reagent plates from storage at 4°C and the nCounter cartridges from storage at -20°C. Allow them to equilibrate to room temperature for 10-15 minutes.

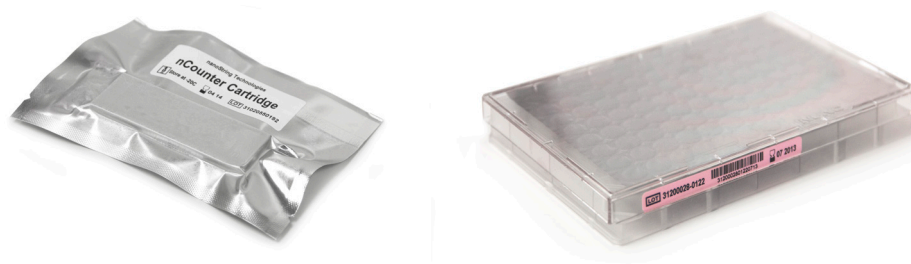


FIGURE 5.8: A sealed sample cartridge (left) and Dx reagent plate (right)



NOTE: Only one reagent plate is required for runs performed using a 1-, 2-, 3-, or 4-test kit.



NOTE: Do not open the cartridge pouch until it has reached room temperature. This will prevent condensation from forming on the cartridge.

- b. Centrifuge the reagent plates at 2000 x g for 2 minutes to collect liquids at the bottom of the wells prior to loading the reagent plates onto the Prep Station deck.
 - c. While the cartridges and plates come to room temperature, continue setting up the Prep Station. Touch **Next**.
- >>> The 'Waste Receptacles' screen will appear.

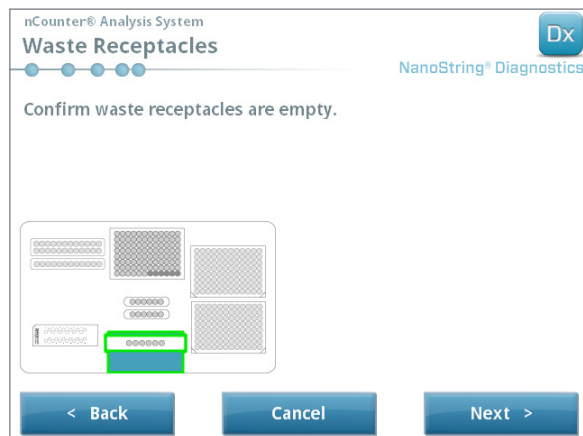


FIGURE 5.9: The 'Waste Receptacles' screen

8. Make sure the disposables from the previous run have been appropriately discarded. Press **Next**.
- >>> The 'Scan Reagent Plate' screen will appear.

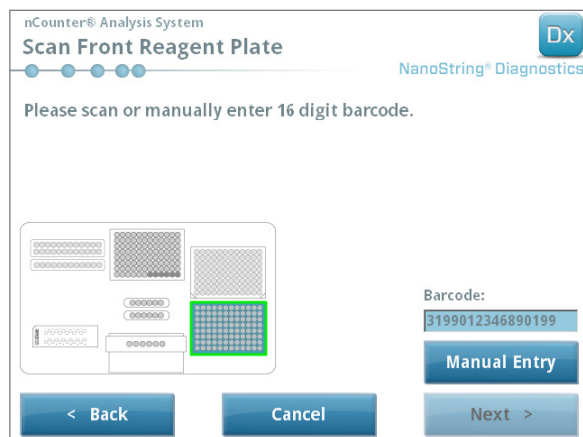


FIGURE 5.10: The 'Scan Reagent Plate' screen

9. Instructions for the 'Reagent Plate' screen:

- a. The barcode for the reagent plates must be scanned before proceeding. Hold the barcode in front of the barcode reader. A red beam will appear. Move the barcode in front of the red beam until it is recorded. When the barcode is successfully recorded, the barcode number will appear in the box and the **Manual Entry** button will change to **Clear Entry**.

If there are problems scanning the barcode, the number can be entered manually. Touch **Manual Entry**; a numeric keypad will appear. Touch the appropriate buttons to enter the number. If you make a mistake, touch **del** to backspace, or **clear** to start over. Press **enter** when finished.

- b. Remove the clear plastic lids and place the reagent plates on the deck as indicated on the screen (**FIGURE 5.10**).

The deck has alignment pins that will allow the plates to sit flat only if they are in the correct orientation. The reagent plate should be oriented with the barcode facing the user (**FIGURE 5.11**). If the plate is placed in the wrong direction, the Prep Station will pause the protocol at the validation step until the user intervenes.



NOTE: Only one reagent plate is required for runs performed using a 1-, 2-, 3-, or 4-test kit. For these kits, load the reagent plate into the front position (nearest the user) on the Prep Station deck.



NOTE: The Prep Station will not accept barcodes for plates that have expired. Make sure the plates are used prior to the expiration date.

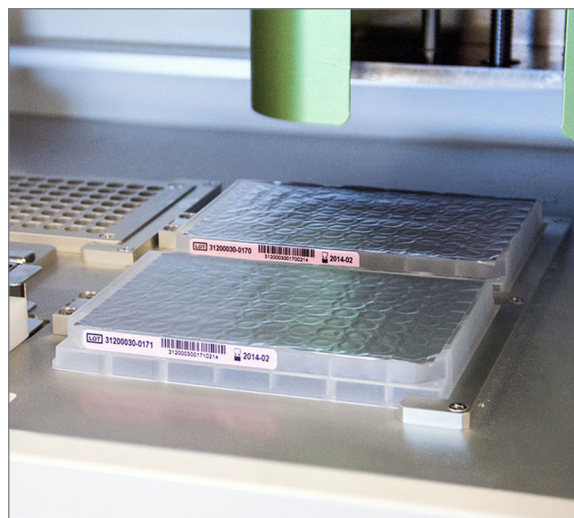
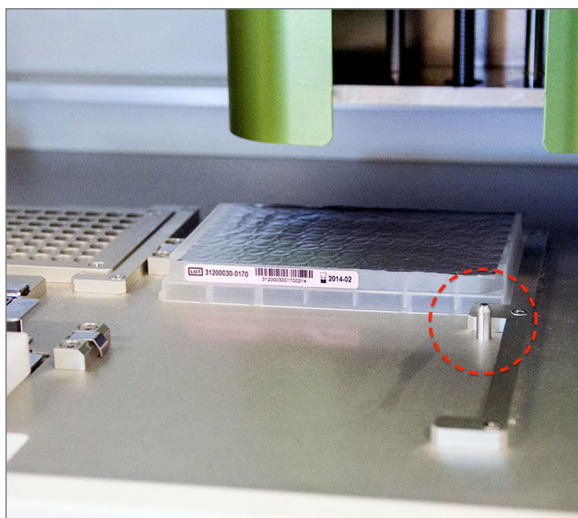


FIGURE 5.11: Use the positioning pins to ensure correct placement of the reagent plates.



IMPORTANT: Do not remove the foil or pierce the wells on the reagent plates. The Prep Station pierces the aluminum foil during processing.

c. Touch **Next**.

>>> The 'Tips and Foil Piercers' screen will appear (**FIGURE 5.12**).

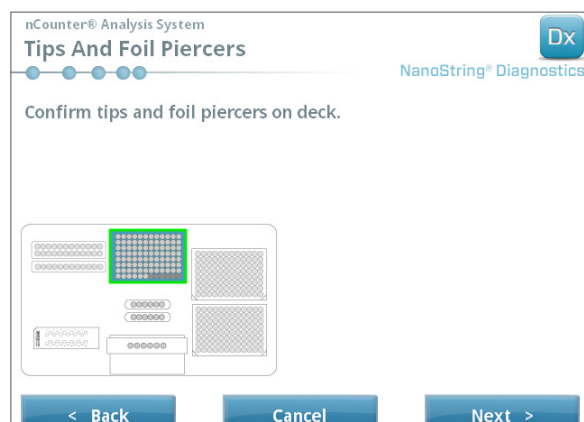


FIGURE 5.12: The 'Tips And Foil Piercers' screen

10. Instructions for the 'Tips and Foil Piercers' screen:

- a. Remove the metal tip carrier from the Prep Station deck by lifting straight up.
- b. Place the tips and the foil piercers into the carrier. Hold the plastic tip rack by the center tabs, hold the tip rack over the metal holder, and slowly lower the tips into the metal holder. It is helpful to place the carrier at eye level to align the plastic tips (**FIGURE 5.13**).

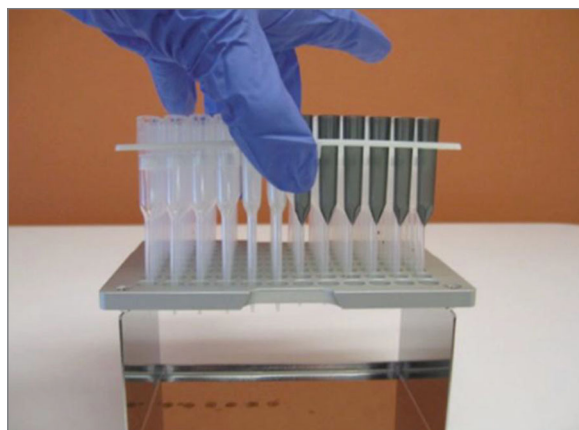


FIGURE 5.13: Insert the tips and foil piercers into metal tip carrier



NOTE: There are two sets of tips nested in each box, with each side of the box containing one set of tips. Hold a hand firmly over the bottom of the box when opening to avoid accidentally spilling the second set of tips.

- c. Replace the loaded metal tip carrier back onto the Prep Station deck with the foil piercers closest to the front of the deck (**FIGURE 5.14**).

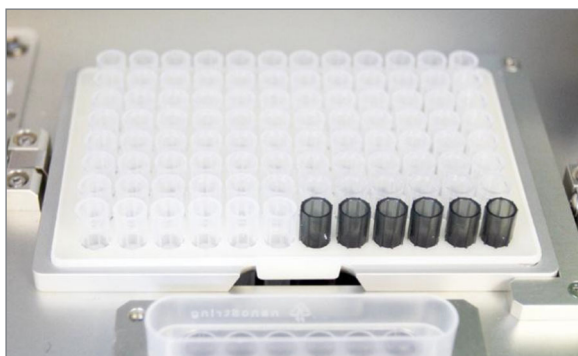


FIGURE 5.14: Proper placement of rack containing pipette tips and foil piercers

- d. Touch **Next**.

>>> The 'Tip Sheaths' screen will appear (**FIGURE 5.15**).

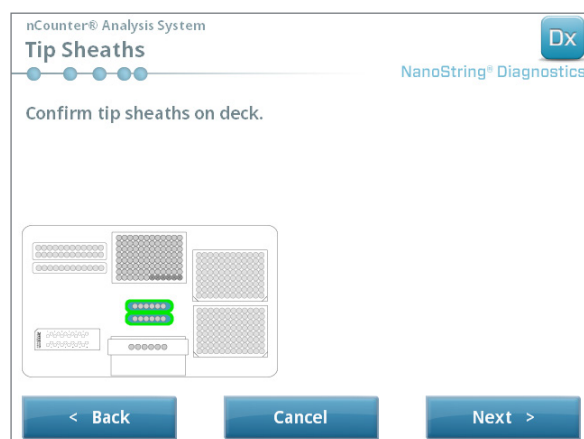


FIGURE 5.15: The 'Tip Sheaths' screen



NOTE: Tip sheaths are used to reduce the amount of consumable waste. They allow the system to dedicate tips to a set of 6 samples and store them while the other 6 samples are being processed.

11. Place the tip sheaths on the deck and press firmly into place. Touch **Next**.

>>> The 'Empty Strip Tubes' screen will appear (**FIGURE 5.16**).

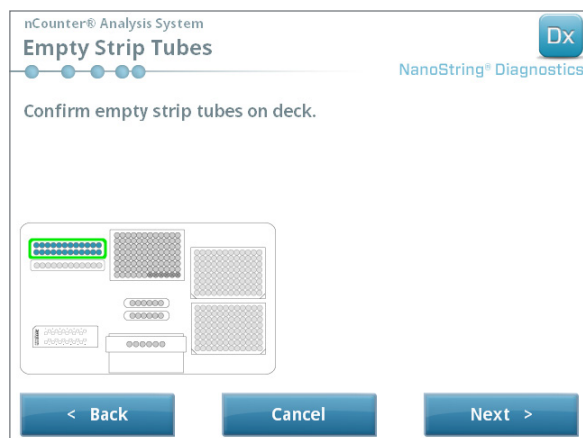


FIGURE 5.16: The 'Empty Strip Tubes' screen

12. Place the empty strip tubes in the heater on the deck. Touch **Next**.

>>> The 'Scan Sample Cartridge' screen will appear.



NOTE: Only one empty heater strip tube is required for runs performed using a 1-, 2-, 3-, or 4-test kit. For these Run Sets, load the empty heater strip tube into the front position of the heat block (nearest the user) on the Prep Station deck.

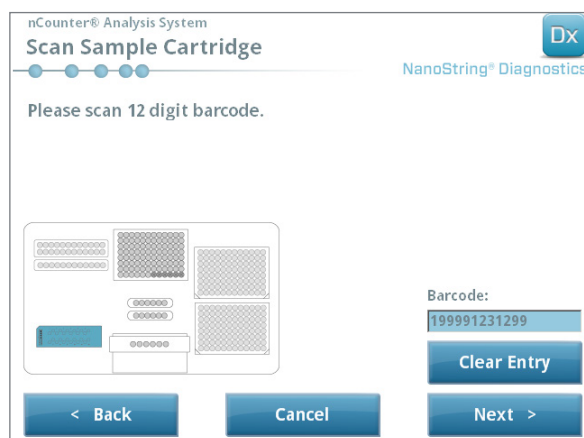


FIGURE 5.17: The 'Scan Sample Cartridge' screen

13. Instructions for the 'Sample Cartridge' screen:

- a. The barcode for the sample cartridge must be scanned before proceeding. Hold the barcode in front of the barcode reader. A red beam will appear. Move the barcode in front of the red beam until it is scanned and the barcode number appears in the entry field.



NOTE: The Prep Station will not accept barcodes for cartridges that have expired. Make sure the cartridge is used prior to its expiration date.



NOTE: It is not possible to manually enter the barcode for the cartridge. If a barcode will not scan or is not accepted, use another cartridge from the same kit lot for the run.

- b. Insert a Sample Cartridge under the electrode fixture in the orientation shown in **FIGURE 5.18**. Place the cartridge on the deck and slide it into position, avoiding the electrodes. Make sure that it is seated completely in the machined depression. When positioned properly, a latch will activate and hold the fixture in place. If it is not seated properly, the electrodes may become bent when the electrode fixture is closed.

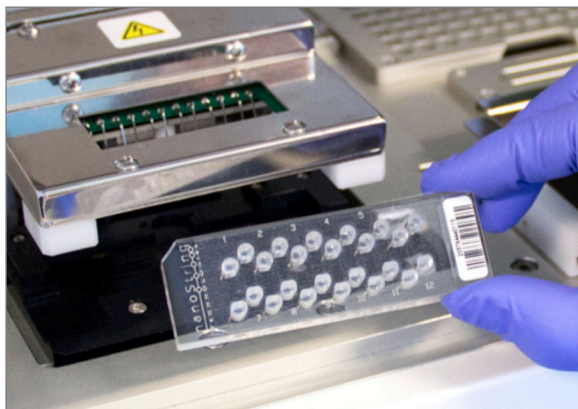


FIGURE 5.18: Insert an unused cartridge into the Prep Station in the orientation shown

- c. Touch **Next**.

>>> The 'Secure Electrode Fixture' screen will appear

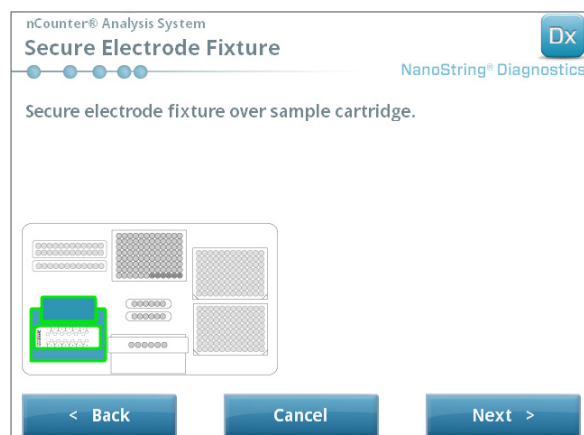


FIGURE 5.19: The 'Secure Electrode Fixture' screen

14. Carefully lower the electrode fixture in place over the cartridge (**FIGURE 5.20**). The 24 electrodes should insert easily into the 24 wells. Touch **Next**.

>>> The 'Hybridized Samples' screen will appear (**FIGURE 5.21**).

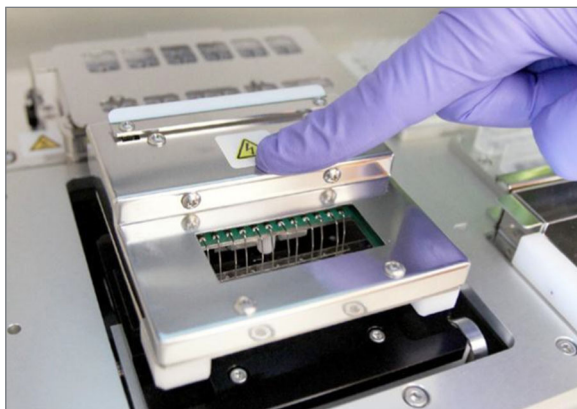


FIGURE 5.20: Carefully lower the electrode fixture into place over the cartridge



IMPORTANT: Do not use the release handle to lower the fixture. Doing so will prevent the fixture from locking. Instead, press on the body of the fixture away from the release handle (**FIGURE 5.20**).



IMPORTANT: If any resistance is felt while lowering the fixture, stop and adjust the position of the cartridge slightly. Make sure that the electrodes are correctly aligned. If the electrodes are not aligned, re-align the electrodes using the 'Align Electrodes' workflow under the Maintenance Menu. The Prep Station will not be able to process any of the samples if there are bent electrodes.

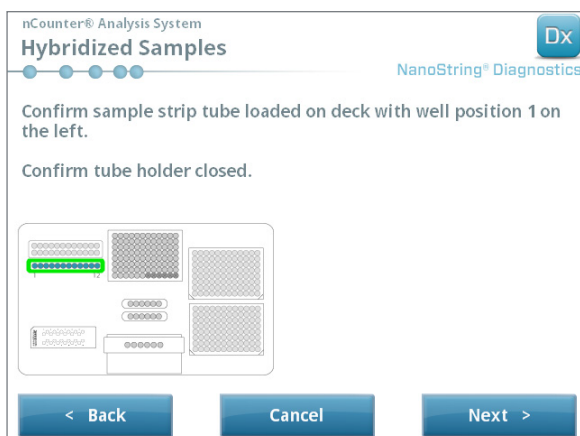
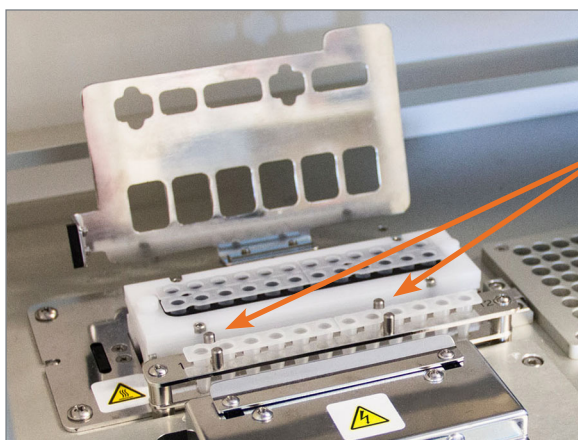


FIGURE 5.21: The 'Hybridized Samples' screen

15. Place the hybridized sample strip tube on the deck of the Prep Station, ensuring that well 1 aligns with position 1 (FIGURE 5.22). Note that the strip tube is asymmetrically keyed, and if the strip tube is placed incorrectly, the lid will not close properly.



Hybridized sample strip tubes have two notches to ensure proper orientation.

FIGURE 5.22: Hybridization sample strip tubes with notched orientation guides



IMPORTANT: Do not let the hybridized samples sit at room temperature longer than 15 minutes. If there are delays between removing the hybridized samples from the heat block and starting the Prep Station, return the samples to 65°C until they can be processed. Do not exceed the maximum hybridization time stated in the assay package insert.



IMPORTANT: All tubes should be seated fully and evenly in the rack to ensure proper processing. Ensure that all tube caps are removed from the hybridized samples prior to placing tubes on the deck. Leaving the caps on will pause the protocol and require user intervention.



IMPORTANT: Only use strip tubes provided by NanoString. Other tubes have different dimensions and will cause system failure.

a. Securely close the lid that flips down over the tubes (**FIGURE 5.23**).

b. Touch **Next**.

>>> The 'Notification Options' screen will appear (**FIGURE 5.24**).

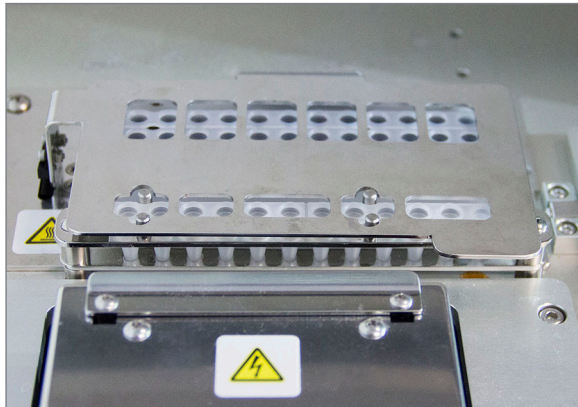


FIGURE 5.23: Lid closed over tubes



IMPORTANT: Failure to securely close the lid over the tubes can result in a system malfunction. If the metal lid is not closed completely, then the sensor will return an error message and the run will not initiate until the error is corrected.

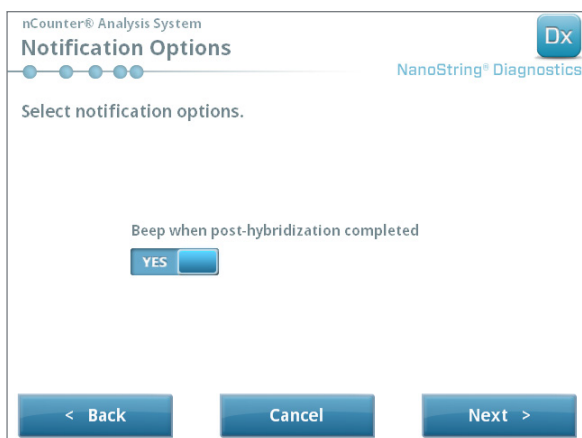


FIGURE 5.24: The 'Notification Options' screen

16. Select whether the Prep Station should make an audible alarm when processing is finished. Touch **Next**.

>>> The 'Start Deck Validation' screen will appear.

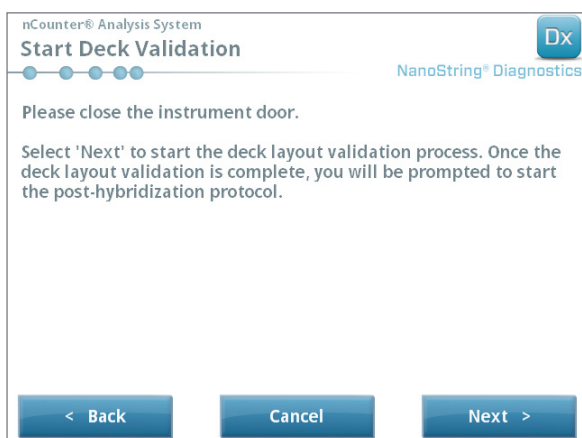


FIGURE 5.25: The 'Start Deck Validation' screen

- a. Touch **Next** to begin validation.

- b. The nCounter Prep Station will now check that all of the consumables and reagents have been placed properly on the deck (**FIGURE 5.26**). To do this, the Prep Station confirms that the sensors for the sample cartridge, electrode fixture, and heater lid are all in the correct state. The pipette head then checks that tips, tip sheaths, strip tubes, and reagent plates are all in place by touching them with a set of validation tips. Do not be alarmed that the Prep Station is touching the consumables; this is a part of normal operation. If the Prep Station determines that a consumable is misplaced, it will instruct the user to fix the configuration.

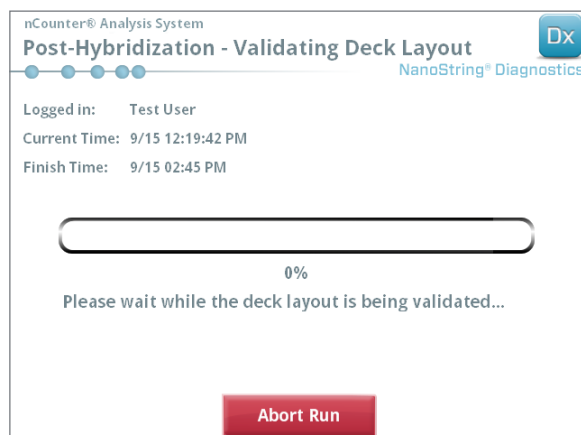


FIGURE 5.26: The 'Post-Hybridization - Validating Deck Layout' screen

- c. After deck validation is complete (**FIGURE 5.27**), a new screen containing the **Start Processing** button will appear. Touch **Start Processing** to initiate the run.

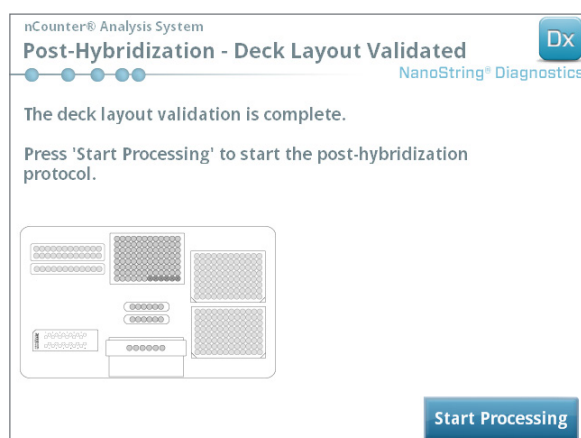


FIGURE 5.27: The 'Post-Hybridization - Deck Layout Validated' screen



IMPORTANT: If a run is paused, resume the run as quickly as possible. The system should not be in a paused state for more than 15 minutes or the test must be repeated for the affected samples.



IMPORTANT: If a run is aborted, the run cannot be restarted and the test must be repeated for the affected samples. See the assay package insert for more information regarding repeat testing.

17. When the sample processing is finished, a blue screen will appear and the timer will start to count up from when the run was completed (**FIGURE 5.28**). Touch **Next**.

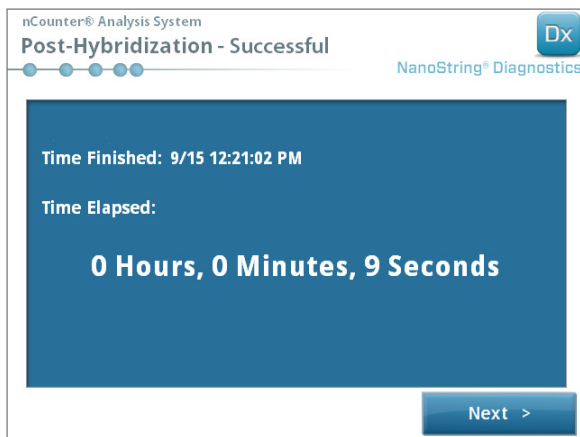


FIGURE 5.28: The System Processing Complete screen

18. The 'Run Successfully Completed' screen lists the steps to follow after sample processing, including:
- Remove and discard empty reagent plates
 - Remove and discard the empty tip racks and foil piercers
 - Remove and discard the sample strips
 - Remove the sample cartridge and seal the wells

19. To release the fixture after the run is complete, pull the latch on the top of the device up and towards the front of the system using a finger as shown in **FIGURE 5.29**.



FIGURE 5.29: Releasing the fixture after a completed run

20. After processing is complete, it is important to do the following:
- a. Seal the wells immediately with the adhesive cover provided to prevent evaporation.
 - b. Samples should be protected from as much light as possible.
 - c. If the cartridge will not be scanned on the Digital Analyzer within an hour the sealed cartridge should be stored at 4°C in an opaque box. The cartridge can be stored this way for up to one week with minimal degradation.
 - d. Empty the waste containers.
21. Touch **Finish** to return to the Main Menu.

6 Operating the Digital Analyzer

A. Initiating a Run

1. To scan a cartridge using the Digital Analyzer, a user must log on to the instrument. In order to log on, touch **Main Menu** on the Welcome screen.

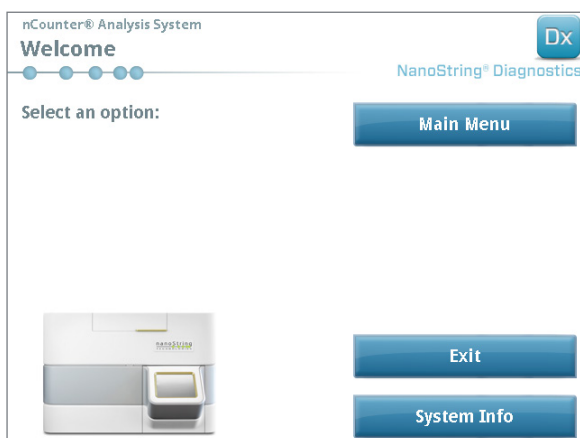


FIGURE 6.1: The Digital Analyzer 'Welcome' screen

2. Enter a valid user name and password and touch **Sign In**.



FIGURE 6.2: The sign in screen

>>> The Main Menu will appear.

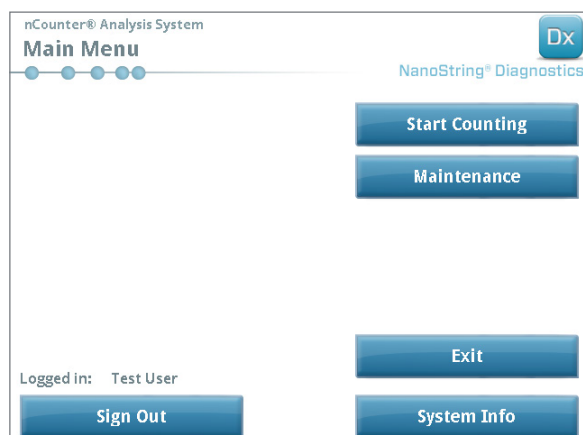


FIGURE 6.3: The Digital Analyzer Main Menu



NOTE: The **Exit** button will only appear on the Welcome screen and Main Menu if the user has the nCounter Dx Analysis System with FLEX configuration (see *Chapter 3 – Selecting the Instrument Mode*).



IMPORTANT: If a laboratory has more than one Digital Analyzer, the cartridge must be scanned on the same instrument registered to the Prep Station that was used earlier to process the samples (see *Chapter 4 – Operating the Web Application*).

3. Place the sample cartridge into an empty slot. Make sure the cartridge is inserted in the correct orientation (the slot and cartridge are keyed to help ensure the correct orientation), and is completely flat in the slot. The barcode will be facing up (FIGURE 6.4). Close the magnetic holder over the cartridge in the slot and close the door to the Digital Analyzer.



FIGURE 6.4: Orient cartridges with the barcode toward the user when placing them into the Digital Analyzer. Close the magnetic clips gently and be sure to push down on the metal plate above the cartridge after the lid is closed to ensure the cartridge lays flat.

- a. Select the **Start Counting** button.

>>> The 'Checking Stage Configuration' screen will appear.

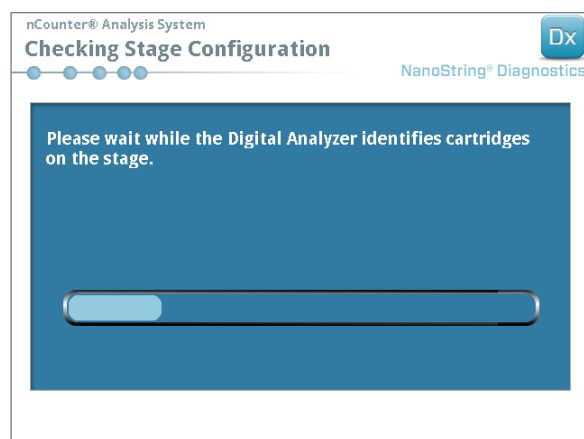


FIGURE 6.5: The 'Checking Stage Configuration' screen



NOTE: The Digital Analyzer tracks which stage positions have already been scanned, are currently in progress, or are waiting to be scanned.

4. The scanner will use the barcode to look up the Run Set associated with that cartridge and determine whether the cartridge is ready to be scanned. Once the six positions have been checked, the Counting Cartridge screen will appear. Each slot has five possible states:
- **Empty location (no graphic)** – This slot is empty and can be loaded with a new cartridge.
 - **White cartridge** – This slot contains a cartridge that is registered, but has not yet been scanned. **DO NOT REMOVE THIS CARTRIDGE.**
 - **Partial blue cartridge** – This slot contains a cartridge that has been incompletely scanned. **DO NOT REMOVE THIS CARTRIDGE.**
 - **Completely blue cartridge** – Scanning of that cartridge is complete.
 - **Icon and text over a cartridge** – There may have been a problem encountered during a scan of the cartridge. Touch the icon or cartridge to get more information.

In the example shown in **FIGURE 6.6**, the cartridge in slot 1 is being scanned and cartridges in slots 2, 3, 4, 5, and 6 are waiting to be scanned.

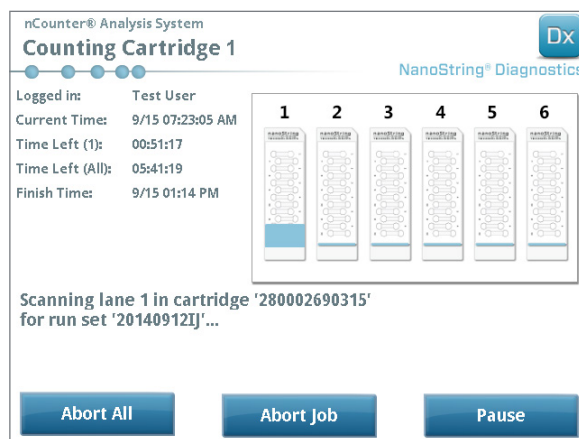


FIGURE 6.6: The 'Counting Cartridge' screen, with the current cartridge indicated



NOTE: Cartridges previously aborted may be able to be re-scanned. When placed in the Digital Analyzer, the counting cartridge screen will display 'ABORTED' for that cartridge. To re-scan a cartridge, press on the cartridge's icon. A screen will appear with the option to scan again. If this is performed while a cartridge is scanning, be aware that the cartridge status will remain pending until either all other cartridges have been scanned or until scanning has been paused and resumed.

5. Confirm that a small blue bar appears at the bottom of the scanning cartridge, indicating the scan has started. There will be a series of rhythmic clicks as the images are collected.
6. To add a cartridge to a Digital Analyzer that is already counting, touch the **Pause** button on the 'Counting Cartridges' screen. It might take a few minutes for the Digital Analyzer to reach a suitable stopping point (**FIGURE 6.7**). The door will unlock when it does. Place the new cartridge in an empty slot, or replace a cartridge that has already been scanned. Touch the **Resume** button. The door should re-lock and resume counting.

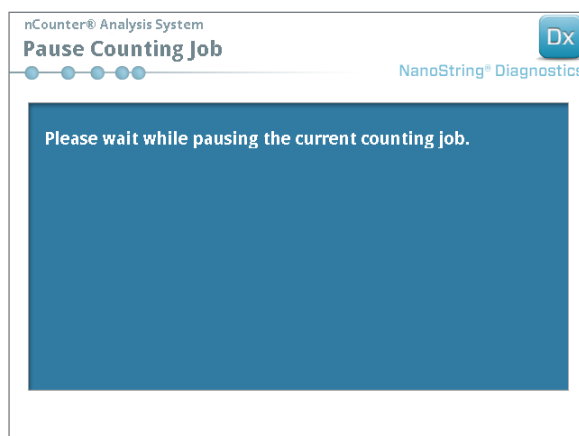


FIGURE 6.7: The 'Pause Counting Job' screen

7. When a cartridge is finished scanning, an e-mail notification will be sent to the user and the processing screen will change to reflect that the cartridge has completed (**FIGURE 6.8**). Upon receiving the e-mail notification that the scan has completed, remove the completed cartridge. In case of an instrument error or reports not being available store cartridge in an opaque box (to protect from light) at 4°C for up to one week. Contact dxsupport@nanosttring.com for assistance.

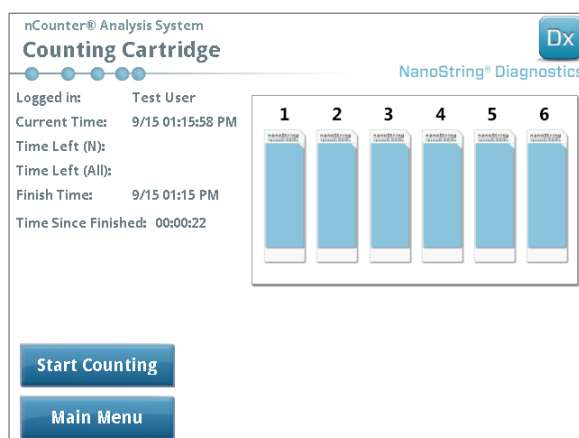


FIGURE 6.8: The 'Counting Cartridge' screen with six completed cartridges

8. Using the link attached to the notification e-mail, open the web interface and download all the diagnostic reports associated with the Run Set just completed as described in *Chapter 4 – Operating the Web Application*.

7 Technical Support and Maintenance

A. Technical Support

Technical support is available by phone, fax, mail, or e-mail. Please be sure to include the product number and serial number in all communications.



U.S. Contact Information:

NanoString Technologies, Inc.

530 Fairview Ave N, Suite 2000

Seattle, WA 98109, U.S.A.

Phone: +1.888.358.NANO (+1.888.358.6266)

Fax: +1.206.378.6288

E-mail: dxsupport@nanosttring.com

Website: www.nanosttring.com

B. Instrument Power Cycling

It is recommended that the system power for each instrument is cycled periodically (for example, once every two weeks after Prep Station O-ring lubrication). Maintenance and support functions can be accessed from the Main Menu of the Prep Station and Digital Analyzer.

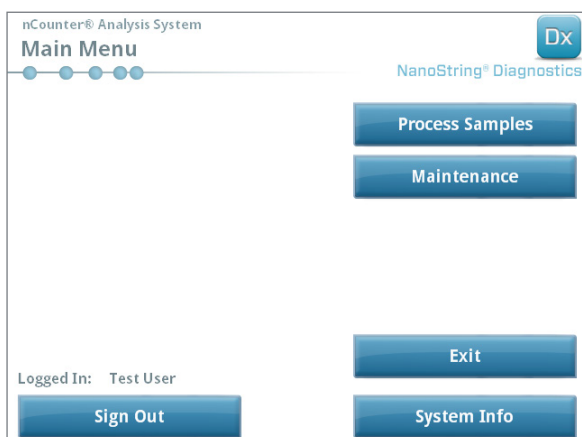


FIGURE 7.1: This example shows the **Maintenance** button on the Prep Station Main Menu.



NOTE: Users must be assigned Administrator privileges by an Administrator to perform these functions. Only Administrators may shut down the system.



NOTE: Shutting down the IVD system will interrupt cartridge preparation and analysis. Please ensure that all cartridges have finished processing on the Digital Analyzer and the Prep Station is not in use before cycling instrument system power.

The following instructions may be used to cycle the system power on either instrument.

1. Select **Power Off** from the Maintenance Menu.

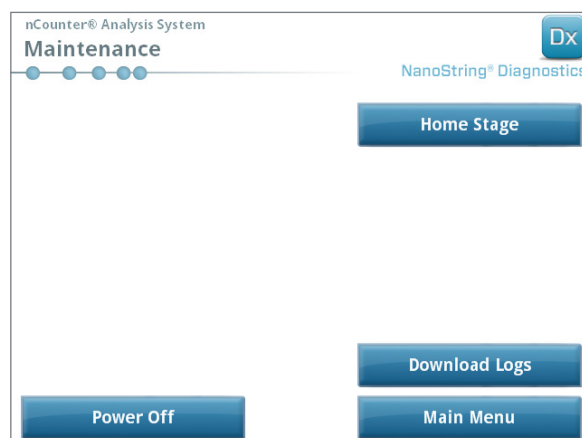
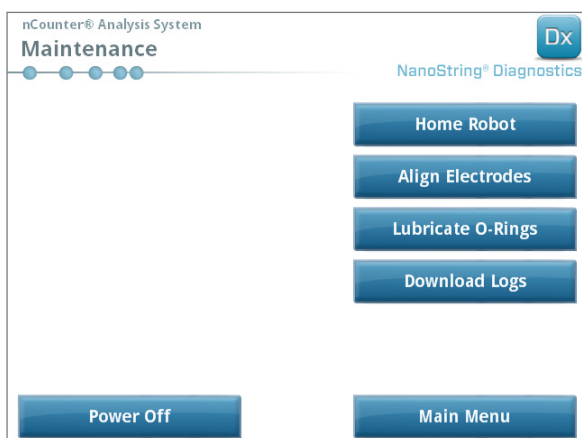


FIGURE 7.2: The Prep Station Maintenance Menu (left) and Digital Analyzer Maintenance Menu (right)

>>> The system will shut down.

2. Select **Confirm** to continue the system shutdown.

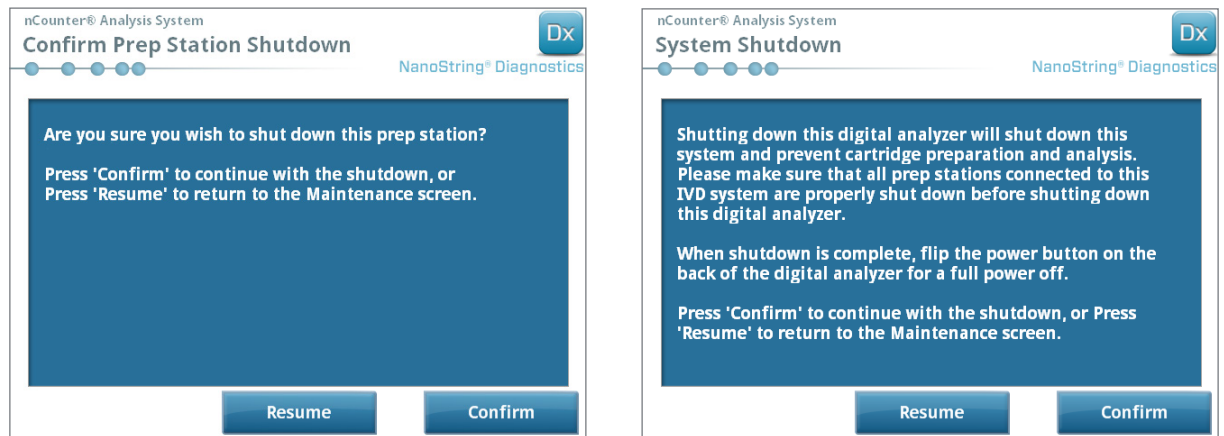


FIGURE 7.3: System shutdown messages displayed by the Prep Station (left) and the Digital Analyzer (right).

>>> A confirmation message will appear.

3. After the system shuts down (there is a delay of approximately 30 seconds), locate the power switch on the back of the instrument and turn off the power.
4. Wait an additional 30 seconds and then use the power switch to restore power to the instrument.

>>> The system will initialize and display the 'Select Instrument Mode' screen (see *Chapter 3 — Selecting the Instrument Mode*).



IMPORTANT: To ensure proper communication between instruments after a power cycle, always restore power to the Digital Analyzer first and allow the instrument to fully initialize before restoring power to the Prep Station.

C. Prep Station Maintenance

Maintenance and support functions can be accessed from the Main Menu of the Prep Station. Users must be assigned the necessary permissions by an Administrator to perform these functions. Only Administrators may shut down the system.

In addition to instrument power cycling (see previous section), users are expected to perform two principal tasks when required: electrode alignment and O-ring lubrication. Additional, less frequent maintenance functions include homing the robot and downloading log files.

Electrode Alignment

From time to time, the electrodes used for stretching the reporters may become bent out of alignment and no longer fit into the cartridge properly. This usually occurs if the cartridge was not aligned properly when the electrode fixture was depressed causing the electrode to make contact with the cartridge and bend. The following describes a method for re-alignment of the electrodes using the system hardware interface. This method allows the electrode fixture to tilt at an angle that makes it much easier to view the electrodes during alignment.

If the electrode is so severely bent that it cannot be inserted into a cartridge, the process outlined below may need to be repeated twice: once without a cartridge present to get the electrodes into roughly the right position so that they can be inserted into a cartridge and a second time with a cartridge present for fine tuning the placement of electrodes within the cartridge wells.



NOTE: The Prep Station checks electrode function during the validation steps of the process, before any processing occurs to the samples. If it detects problems with an electrode, the processing will halt and wait for user intervention. The screens described below will then appear, allowing the user to fix the bent electrodes.

1. Select **Align Electrodes** from the Maintenance Menu.

>>> The 'Align Electrodes Start' screen will appear.

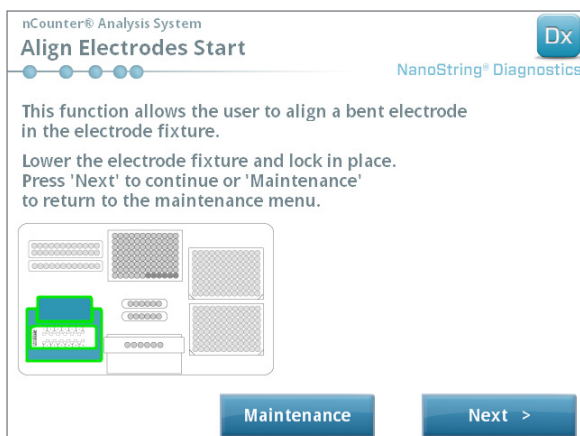


FIGURE 7.4: The 'Align Electrodes Start' screen, step 1 of 5

2. If the electrode is severely bent to the point where a cartridge cannot be inserted, close the electrode fixture without a cartridge in it and adjust the position of the electrode such that it is positioned similarly to the other electrodes. If it is only slightly bent and a cartridge can be inserted by carefully maneuvering the bent electrode, then insert a cartridge before closing the electrode fixture. Touch **Next**.

>>> The 'Align Electrodes Close Door' screen will appear.

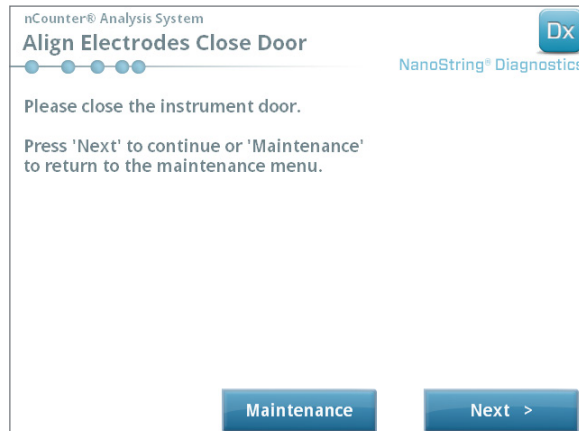


FIGURE 7.5: The 'Align Electrodes Close Door' screen, step 2 of 5

3. Close the door and touch **Next**.

>>> While the door is closed, the electrode fixture tilts towards the operator for easier access to the electrodes. Two screens follow in succession (FIGURE 7.6).

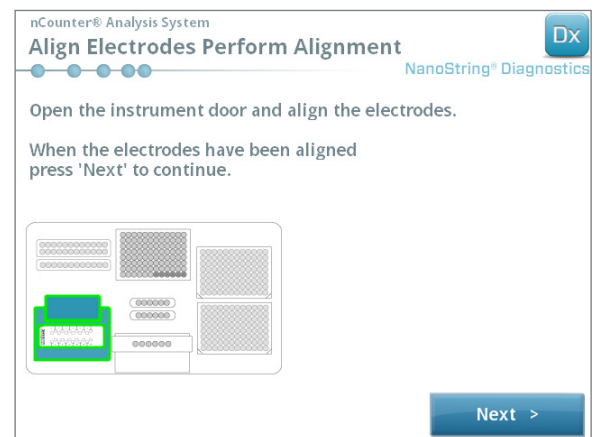
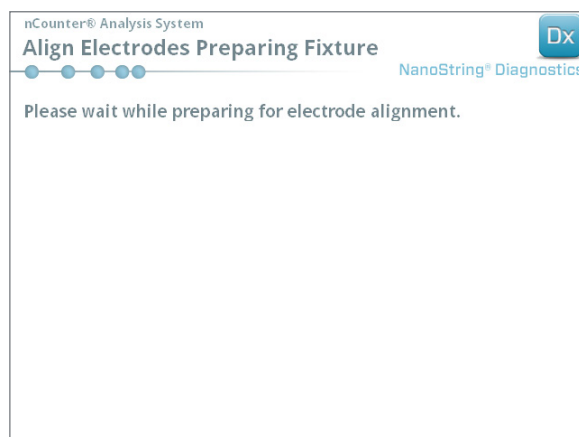


FIGURE 7.6: The 'Align Electrodes' progress screens, steps 3 and 4 of 5

4. Using a pair of tweezers, gently bend the electrodes into alignment by trying to align the tip of the electrode to the center and bottom of the cartridge well. Touch **Next**.

>>> The final screen will appear when the procedure is complete.

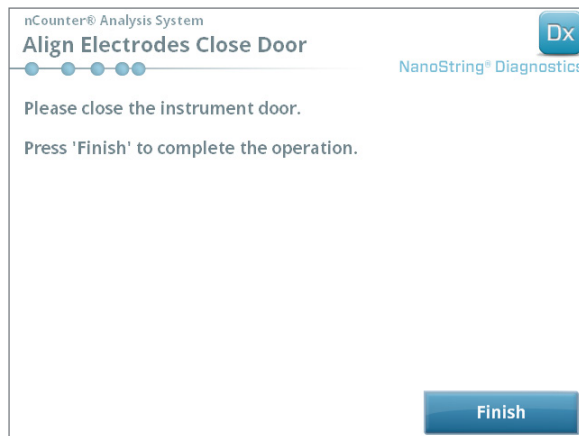


FIGURE 7.7: The 'Align Electrodes Close Door' screen, step 5 of 5

5. Close the door, and touch **Finish**. The electrode fixture will tilt back to its home position, and then the Maintenance Menu will be displayed.

O-ring Lubrication

The O-rings on the pipetting nozzles in the Prep Station are present to ensure a seal with the pipette tips thus ensuring accurate liquid volume control. O-rings are the small black rings found on the lower end of the nozzle. These O-rings must be lubricated regularly in order to ensure a good seal.

The Prep Station Maintenance Menu has an interface to facilitate O-ring lubrication by bringing the pipetting head to the front of the deck for easy access.



NOTE: An icon will appear on the Main Menu and Maintenance Menu when it is necessary to lubricate the O-rings (FIGURE 7.8).

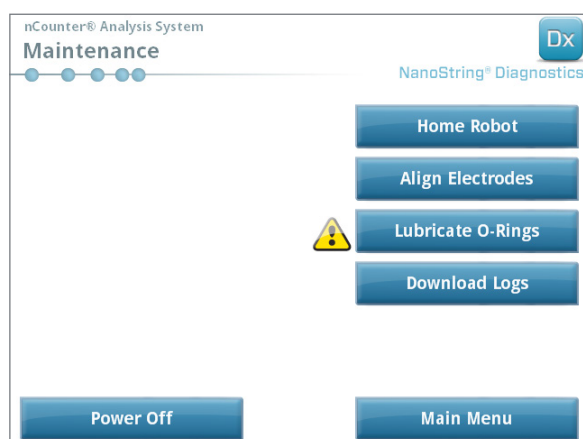


FIGURE 7.8: The yellow 'Lubricate O-rings' symbol



CAUTION: When performing maintenance functions, always use appropriate safety precautions including wearing safety glasses and gloves.

Some materials are required but not provided with the kit:

- Silicone grease (provided during system installation)
- Lint-free paper (e.g., Kimwipe™ by Kimberly-Clark®)
- Gloves



IMPORTANT: DO NOT USE ANYTHING OTHER THAN THE SUPPLIED SILICONE GREASE ON O-RINGS.

1. Select **Lubricate O-rings** on the Maintenance Menu.

>>> A series of 'Lubricate O-rings' maintenance screens will appear.

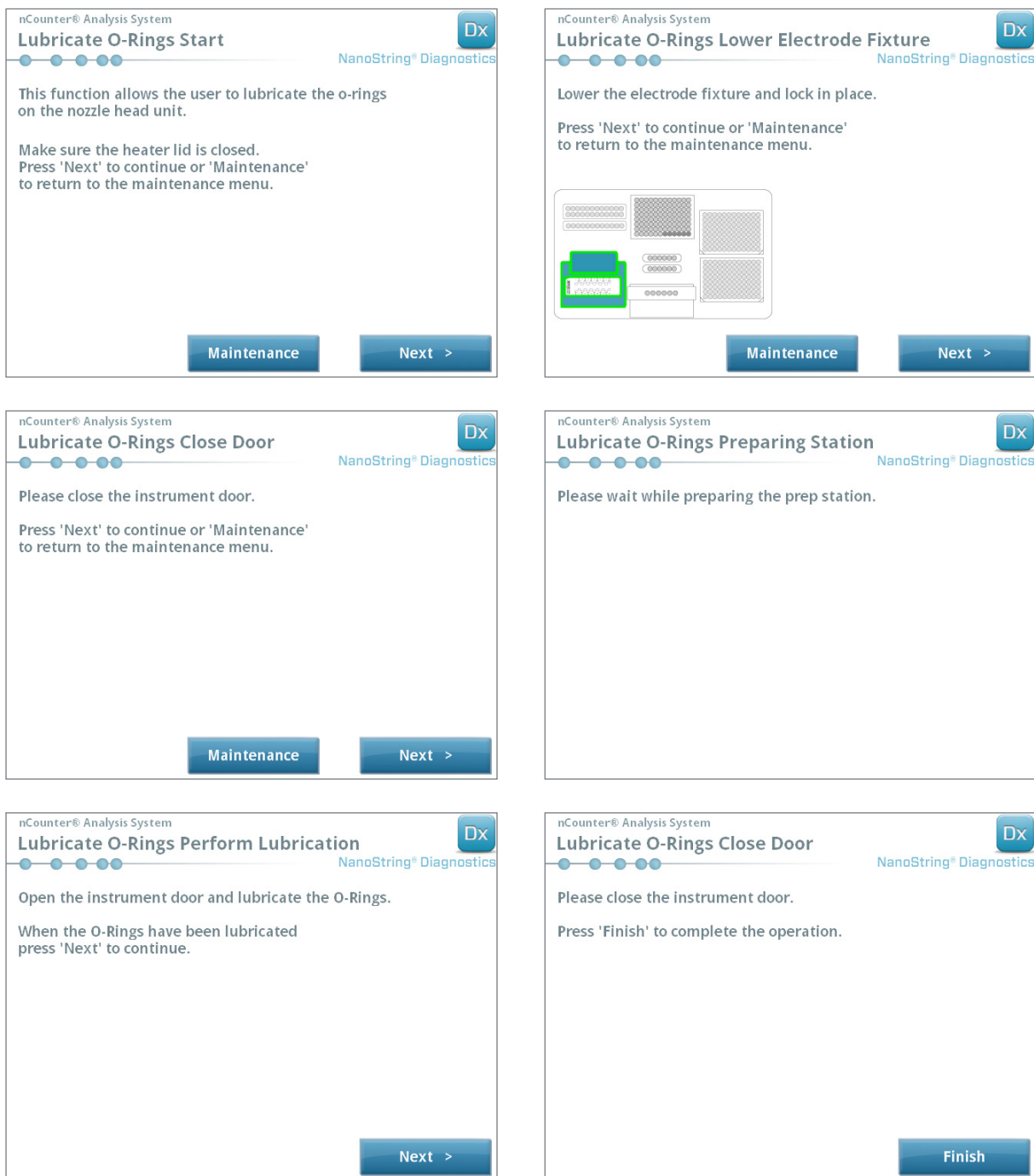


FIGURE 7.9: Screens shown for the different steps in the Lubricate O-rings workflow.

2. Follow the directions on the screens.
3. To lubricate the O-rings, take a small amount of silicone grease and rub a finger round the O-ring using a gloved hand as shown in **FIGURE 7.10**.

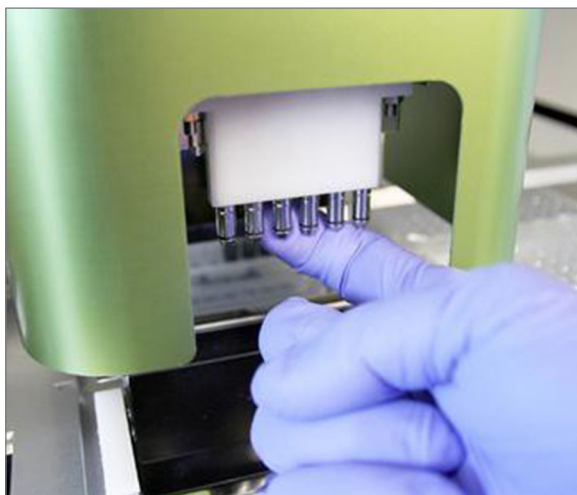


FIGURE 7.10: Use a finger to apply a small amount of NanoString silicone grease to the O-rings

4. Using lint-free paper, thoroughly wipe off any excess silicone grease from the nozzles and Tip Ejectors.
5. Gently move that finger around each ring to distribute the grease evenly.
6. Following the instructions on the screen, touch the **Next** and **Finish** buttons to complete the procedure.
7. Completing the 'Lubricate O-rings' workflow will reset the internal timer and remove the yellow warning icon if it is present.



IMPORTANT: Excess grease may cause equipment malfunction. Avoid applying grease to the metal portion of the nozzle.

Downloading Log Files

If an issue is encountered, NanoString Support may request a download of the system log files. In the Maintenance Menu, select the **Download Logs** button. Log files are stored according to the date of each run (FIGURE 7.11). Multiple dated folders may be selected for download by touching each one. Selected folders will be highlighted in blue.

1. Insert a USB flash drive into the Prep Station's front USB port.
2. When the desired folders have been selected, touch **Download** to transfer them to the flash drive.

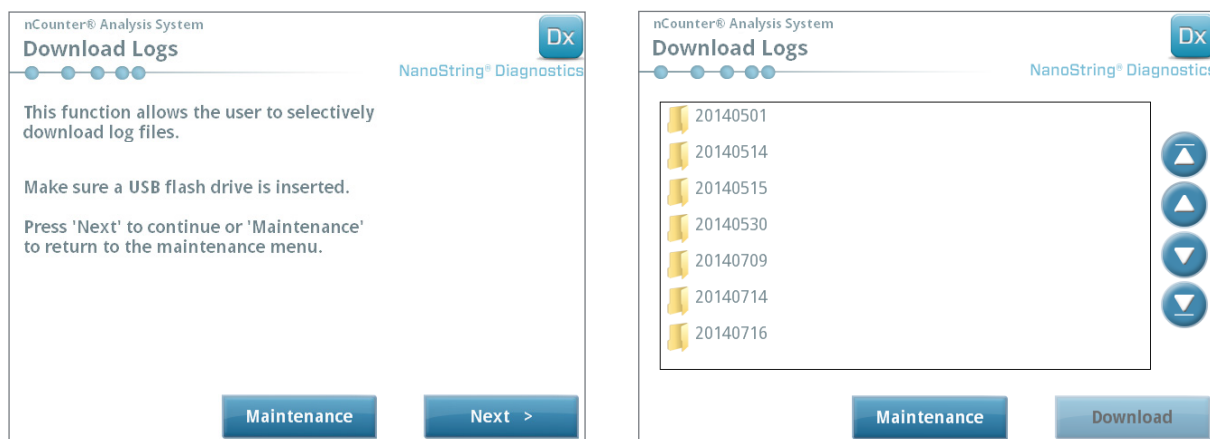


FIGURE 7.11: Screens that appear when downloading log files

Home Robot

If the robot enters into an undesirable state, selecting the **Home Robot** button can home all the motors. This button should not be needed under normal operation.

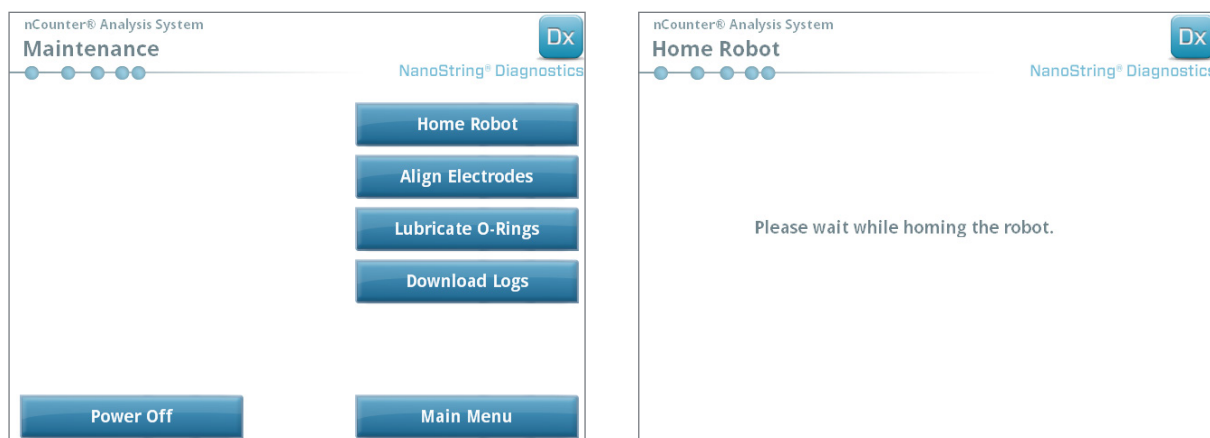


FIGURE 7.12: Screens that appear during the Home Robot process

D. Digital Analyzer Maintenance

Maintenance and support functions can be accessed from the Main Menu of the Digital Analyzer. Users must be assigned the necessary permissions by an Administrator to perform these functions. Only Administrators may shut down the system.



IMPORTANT: If the Digital Analyzer is shut down, the web application will be unavailable and the Prep Station will be inoperable.

The Digital Analyzer has been designed to require no maintenance other than instrument power cycling (see previous section). However, if any issues occur, NanoString Support may request a download of the log files.

Downloading Log Files

In the Maintenance Menu, select the **Download Logs** button. Log files are stored according to the date of each run. Multiple dated folders may be selected for download by touching each one. Selected folders will be highlighted in blue.

1. Insert a USB flash drive into the Digital Analyzer's front USB port.
2. When the correct folders have been selected, touch **Download** to transfer them to the flash drive.

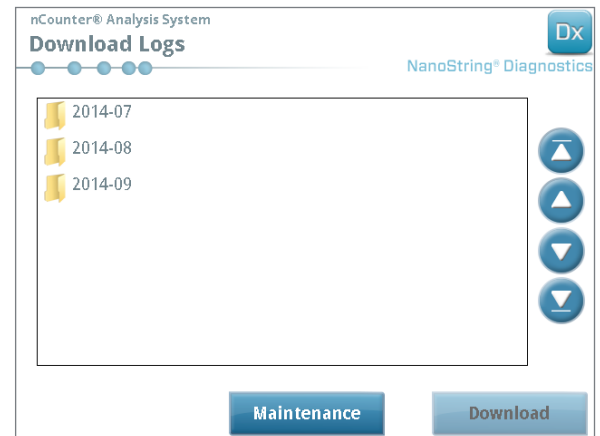
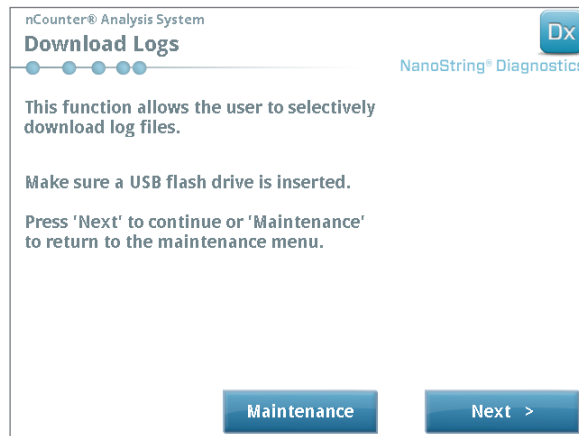


FIGURE 7.13: Screens that appear when downloading log files

E. Cleaning Instructions

Follow all safety and operating instructions provided in this manual. Use safe laboratory operating precautions, including personal protective equipment such as safety glasses and gloves.

Prep Station

After a completed run, remove all consumables and waste.

Periodically, clean the stage surface and waste receptacles of the Prep Station by wiping with a disinfectant followed by wiping with water or 70% ethanol. Avoid the electrode fixture. An RNase removal agent such as RNaseZap® from Ambion® may also be used.

Clean the exterior periodically using a diluted neutral soap followed by water. Use a damp towel rather than spraying directly on the instrument.

Digital Analyzer

Clean the exterior periodically using a diluted neutral soap followed by water. Use a damp towel rather than spraying directly on the instrument.

F. Disposal of Electronic Equipment

















IMPORTANT: This symbol on the nCounter Dx Analysis System is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this marking on the product indicates that:

- The device was put on the European Market after August 13, 2005.
- The device is not to be disposed via the municipal waste collection system of any member state of the European Union.

For products under the requirement of WEEE directive, please contact your dealer or local NanoString office for the proper decontamination information and take back program, which will facilitate the proper collection, treatment, recovery, recycling, and safe disposal of the device.

Symbols and Definitions

	— Manufacturer
	— Authorized Representative in the European Community
	— <i>In vitro</i> diagnostic medical device
	— Consult Instructions for Use
	— CE Mark
	— Catalogue or Reference Number
	— Batch code / Lot number
	— Serial number
	— Contains sufficient for <n> tests
	— Temperature range storage conditions
	— Lower limit of temperature storage conditions
	— Upper limit of temperature storage conditions
	— For Use by / Expiry Date
	— Date of manufacture

Room Temp. = Room Temperature

HYB = Hybridization

Regulatory Disclaimer

For *in vitro* diagnostic use.

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